

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF ARIZONA
3

4
5 In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
6 Products Liability Litigation)
7) Phoenix, Arizona
8) May 29, 2018
9 Doris Jones, an individual,) 1:00 p.m.
10)
11 Plaintiff,)
12) CV 16-00782-PHX-DGC
13 vs.)
14)
15 C.R. Bard, Inc., a New)
16 Jersey corporation; and Bard)
17 Peripheral Vascular, Inc., an)
18 Arizona corporation,)
19)
20 Defendants.)
21)
22)
23)
24)
25)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(Jury Trial - Day 9 - P.M. Session)
(Pages 1993 through 2130, inclusive.)

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21 I N D E X

22 WITNESS:

23 DIRECT24 CROSS25 REDIRECTRECROSS

26 MELANIE SUSSMAN

27 By Video Deposition

28 (Resumed)

1996

29 JOHN VAN VLEET

30 By Mr. Rogers

1996

2081

31 By Mr. Clark

2065

32 ROB CARR

33 By Mr. North

2083

<u>EXHIBIT</u>	<u>INDEX OF EXHIBITS</u>	<u>RECEIVED</u>
5169	Apr. 25, 2003 Recovery Retrievable Abbreviated 510(k)	2105
5177	Nov. 27, 2002 FDA Clearance Letter Re Recovery Permanent (Substantial Equivalence)	2104
5178	Oct. 25, 2002 Letter IMPRA to FDA Re Recovery	2103
5179	Oct. 4, 2002 Letter FDA to IMPRA Re Recovery	2102
5182	Aug. 30, 2002 Letter IMPRA to FDA Re Recovery	2100
5187	Aug. 5, 2002 Letter FDA to IMPRA Re Recovery	2098
5197	July 25, 2003 FDA Clearance Letter Re Recovery Retrievable (Substantial Equivalence)	2107
5252	ETR-04-03-02 (RNF v. Competitive Product -- migration resistance)	2117
5301	ETR-05-01-06 Animal Model Evaluation of Recovery Filter G1A Femoral System Report	2110
5304	ETR 05-02-11 G1A Recovery Filter Femoral System Chronic Animal Study Report	2111
5315	Phase 2 Design Review G1A Recovery Filter Femoral Delivery System	2123
5316	Phase 3 Design Review (Design Review 3 & 4) G1A Recovery Filter Femoral Delivery System	2124
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P R O C E E D I N G S

THE COURT: Ladies and Gentlemen, for your information we will go until 4:20 today as I have a 4:30 hearing.

Counsel, let's go ahead and continue playing the deposition.

(Video testimony of Melanie Sussman resumed.)

MR. ROGERS: Your Honor, at this time the defense calls John Van Vleet.

THE COURTROOM DEPUTY: Mr. Van Vleet, if you will please come forward. Stand right here and raise your right hand, please.

(The witness was sworn.)

THE COURTROOM DEPUTY: Could you state and spell your name for the record, sir?

THE WITNESS: Sure. It's John, J-O-H-N, D. as in David, Van Vleet, V-A-N capital V-L-E-E-T.

THE COURTROOM DEPUTY: Thank you, sir. Please come have a seat.

JOHN D. VAN VLEET,
called as a witness herein, having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. ROGERS:

Q. Mr. Van Vleet, can you introduce yourself to the jury,

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1 please?

2 A. Sure. My name is John Van Vleet.

3 Q. And let's get one thing out of the way right out of the box
4 which I'm sure everyone is wondering about. What's up with
5 your leg?

01:06PM

6 A. I have a repeated injury to my left ACL so I'm in the
7 middle of a two-stage revision.

8 Q. Mr. Van Vleet, have you ever been an employee of C.R. Bard?

9 A. Yes, I have.

10 Q. What years were you employed at C.R. Bard?

01:06PM

11 A. I began working for Bard in June of 2007.

12 Q. And what -- well, when did you leave Bard?

13 A. At the end of the calendar year last year.

14 Q. So at the end of 2017?

15 A. Correct.

01:06PM

16 Q. Can you tell the jury what you are doing now, please?

17 A. Sure. My position at Bard was the Vice President of
18 Regulatory and Clinical Affairs and it's exactly the same job
19 I'm doing for a smaller company based in Boston, Corindus
20 Vascular Robotics.

01:07PM

21 Q. Do you currently live in Phoenix?

22 A. I live in Tempe.

23 Q. How long have you lived in the Phoenix area?

24 A. Since 2007.

25 Q. And with your new job, are you going to remain in the

01:07PM

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1 Phoenix area?

2 A. I will.

3 Q. So you are able to work for this Boston company remotely
4 and live in Phoenix?

5 A. Correct. I will be in the office a week of the month.

01:07PM

6 Q. Mr. Van Vleet, do you have family here?

7 A. I do.

8 Q. Tell us about your family.

9 A. Let's see. I have my 90-almost-3-year-old mother, my wife,
10 and two of our three children live here. And then I have two
11 adult children that live in Michigan.

01:07PM

12 Q. Mr. Van Vleet, let's talk a little bit more about your time
13 at Bard. Were you an employee of the Peripheral Vascular
14 Division?

15 A. Yes, I was.

01:07PM

16 Q. And tell us what your -- what you did in your role as the
17 VP of Regulatory Clinical Affairs?

18 A. So essentially, my responsibilities were to interface with
19 all ministries of health throughout the world in the countries
20 in which we sold our products. In the U.S. that would be the
21 FDA. And in the cases where those products required a higher
22 level of data, such as human clinical trials, then our teams
23 would need to design and conduct clinical trials to collect
24 those data.

01:08PM

25 Q. Did your job entail communications with the FDA?

01:08PM

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1 A. Yes.

2 Q. And how frequently were you in communication with the FDA?

3 A. At least once a week.

4 Q. Mr. Van Vleet, before I ask you some questions about your
5 education, tell us where you were born, please.

01:08PM

6 A. Sure. I was born about 40 miles from the Haitian border in
7 the Dominican Republic. I was youngest son of four missionary
8 parents.

9 Q. When did you come to the United States?

10 A. I came to go to University in 1977.

01:08PM

11 Q. What year did you finish?

12 A. Well, I changed majors a few times and I was working full
13 time. I graduated in 2003.

14 Q. What was your degree that you finished with?

15 A. A Bachelor of Science in biology with a minor in chemistry.

01:09PM

16 Q. Are you also -- do you have a degree in medical technology?

17 A. I did a 12-month internship and took the boards and
18 received my license from the American Society of Clinical
19 Pathologists in 1984.

20 Q. What does a medical technologist do?

01:09PM

21 A. So in order to conduct and analyze samples collected from
22 patients, human patients, a team of pathologists are supported
23 by med techs, licensed med techs, who then have been
24 specifically trained to conduct these studies.

25 Q. Does that involve a lot of work in a laboratory?

01:09PM

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1 A. Yes.

2 Q. And Mr. Van Vleet, do you have a Master's Degree?

3 A. I do.

4 Q. In what?

5 A. I have a Master's of Science in management with a minor in
6 marketing from Marian College.

01:10PM

7 Q. Did you start off your work life in the medical device
8 industry?

9 A. No.

10 Q. And can you tell us the journey you went through to get to
11 the medical device industry?

01:10PM

12 A. Sure. I had the good fortune of finding a job in a
13 hospital system in Fort Wayne, Indiana, where I worked at the
14 time. And they had tuition reimbursement, which is how I was
15 able to pay for my college. But after I finished my licensure
16 in medical technology, I was unable to find a position in the
17 field of medicine. So I focused on analytical laboratory type
18 of work and I worked analyzing fuels and lubricants and coal
19 and different things like this, basically leveraging my lab
20 skills and then also worked briefly as the manager of a
21 hazardous waste testing landfill.

01:10PM

01:10PM

22 And it was at that time that I was finishing my
23 Master's and I met the person that offered me my first job in
24 medical devices 30 years ago at Bristol-Myers Squibb Orthopedic
25 Division-Zimmer.

01:11PM

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1 Q. Have you been in the medical device industry since that
2 time?

3 A. I have been lucky enough to be there, yes.

4 Q. That's been for about 30 years?

5 A. Yes.

01:11PM

6 Q. Why have you devoted your career to the field of medical
7 devices?

8 A. For me, it offered me an opportunity to be involved in the
9 delivery of care to patients. I missed not working in the
10 hospital because I did patient care in the hospital. But this
11 almost brings both worlds together. You still have an impact
12 and you are still delivering care to patients, but you have
13 better working hours.

01:11PM

14 Q. Let's turn our attention, I guess, to your work at C.R.
15 Bard. And I think you told us that you came to Bard in 2007,
16 is that right?

01:11PM

17 A. June of 2007.

18 Q. So at that point in time, what IVC filter was on the
19 market?

20 A. At that time, the G2 Filter was on the market for permanent
21 indication.

01:11PM

22 Q. And did you have responsibilities for the G2 Filter?

23 A. I did.

24 Q. And what was the first project that you were involved in
25 regarding the G2 Filter?

01:12PM

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1 A. So the study of -- for the submission to the FDA had been
2 essentially completed. The data were being scrubbed and they
3 were being analyzed. So essentially, it was to take those data
4 and oversee or help write the clinical study report that would
5 be submitted to FDA.

01:12PM

6 Q. When you are referring to a clinical study, are you
7 referring to the EVEREST study?

8 A. I am.

9 Q. So when you arrived in 2007, had the G2 already been on the
10 market?

01:12PM

11 A. Yes.

12 Q. And about how long had it been on the market?

13 A. Maybe a year or a couple years. Actually, I think it was
14 two years. Two years. Yeah.

15 Q. And when it was originally cleared and made it into the
16 marketplace, was the G2 indicated for permanent retrieval -- or
17 excuse me -- as a permanent filter?

01:12PM

18 A. Yes.

19 Q. And so the purpose of EVEREST was what?

20 A. To evaluate the safety of being able to retrieve the device
21 when it was no longer clinically necessary.

01:13PM

22 Q. And Mr. Van Vleet, was it necessary for you to educate
23 yourself as part of the process of getting up to speed to do
24 your job about what had happened historically with the G2
25 Filter?

01:13PM

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1 A. Yes.

2 Q. And once you were involved in the EVEREST study, did you
3 have communications with FDA about that study?

4 A. Yes.

5 MR. ROGERS: Can we pull up Exhibit 5333, please.

01:13PM

6 And, Your Honor, this is in evidence since this
7 morning, I believe. May we publish?

8 THE COURT: You may.

9 BY MR. ROGERS:

10 Q. Mr. Van Vleet, can you see on your screen this exhibit?

01:13PM

11 A. I can.

12 Q. And can you tell the jury what this is?

13 A. This is an IDE annual progress report. IDE stands for
14 Investigational Device Exemption which is the process by which
15 FDA grants manufacturer the permission to conduct trial or a
16 study of a device that's not included in its current approved
17 labeling. That's a long story.

01:14PM

18 Q. When you say "approved labeling" do you mean cleared
19 labeling?

20 A. Cleared labeling. Yes. Correct.

01:14PM

21 Q. What is the distinction between those two things, cleared
22 and approved?

23 A. Sure. So the IVC filter family of products are Class II
24 products. Those are cleared through an application process
25 called the 510(k) process. Class III devices are cleared

01:14PM

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1 through a usually clinical trial but what's call a PMA process,
2 or premarket approval application and that's generally a longer
3 process as well.

4 Q. And of all the Bard IVC filter products that are
5 retrievable, have they all been through the 510(k) clearance
6 process?

01:14PM

7 A. Yes, sir.

8 Q. Mr. Van Vleet, can you describe for the jury just generally
9 what the purpose of this document is?

10 A. So there is a requirement on an annual basis to provide a
11 comprehensive summary of mostly the adverse events that are
12 collected in the study, because frequently you don't have all
13 of the data points for all the primarium points. And so it's
14 kind of a status report of the study. You actually do two
15 different reports: One every six months as a listing of
16 investigators or people that are actually doing the study and
17 confirming that they have institutional permission to do that;
18 and then this is the more extensive listing of all the adverse
19 events.

01:15PM

01:15PM

20 MR. ROGERS: Scott, would you mind going to Page 33.

01:15PM

21 BY MR. ROGERS:

22 Q. Down at the bottom, Mr. Van Vleet, do you see where it says
23 3.7?

24 A. Yes.

25 Q. Can you read for the jury what that is?

01:15PM

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1 A. Summary of anticipated and unanticipated adverse effects.
2 The study utilizes an independent physician who acts as a
3 medical monitor. The medical monitor's role is to ensure an
4 unbiased assessment of adverse events and responsible for the
5 review and validation of all reported adverse events that are
6 considered serious, device and/or procedure related and that
7 occur during the course of the study.

01:16PM

8 Q. And so is this where you are periodically providing to FDA
9 information about adverse events that happened during the
10 EVEREST study?

01:16PM

11 A. Yes.

12 MR. ROGERS: Let's go to Page 57, please. And can you
13 rotate that? Can you pull that chart out, I guess, so it's a
14 little bigger maybe?

15 BY MR. ROGERS:

01:16PM

16 Q. Mr. Van Vleet, can you see that okay?

17 A. I can.

18 Q. Can you tell the jury what we're looking at here?

19 A. This is just a detail listing of all complications that
20 would have been reported in the study. FDA called them adverse
21 events.

01:17PM

22 Q. And so if an event occurs during the EVEREST study, is Bard
23 obligated to report that?

24 A. Yes.

25 Q. And let's go on to Page 70, please.

01:17PM

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1 Can you pull that table out?

2 And just so we're oriented, Mr. Van Vleet, I want to
3 ask you what some of these columns are. On the far left looks
4 like there's a column called "patient number." What is that?

5 A. So that's a code that's assigned to the patient to
6 de-identify them and protect their anonymity.

01:17PM

7 Q. Then there's a column called "AE number." What is that?

8 A. That is a number -- I'm just trying to orient myself.

9 Okay. So that would be if a patient has an adverse event, they
10 first have their own identifier, and then that adverse event
11 would be Number 1. If they have more than one, the next is
12 Number 2, 3, 4, et cetera.

01:17PM

13 Q. How about that next column that says, "preferred term."
14 What is that?

15 A. Sure. So FDA prefers, and the clinical community prefers
16 that we use a pre-agreed upon listing of names, in other words,
17 that we're always calling the condition or whatever happens the
18 same thing every single time. So that's the preferred name
19 that usually is agreed upon before, or there is a glossary that
20 is included.

01:18PM

01:18PM

21 Q. And moving across the page there is a column that says
22 "event." Do you see that underneath "investigator assessment"?

23 A. Yes, sir.

24 Q. What is that?

25 A. So that's just basically kind of a more detailed

01:18PM

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1 description of actually what the complication was.

2 Q. And then following that, there's a column called "SAE." Do
3 you see that?

4 A. Yes.

5 Q. What does that stand for?

01:18PM

6 A. That stands for Serious Advice Effect or Event.

7 Q. And there are some Ns we see underneath that. Does that
8 get coded as either N or Y?

9 A. Yes.

10 Q. For yes or no?

01:19PM

11 A. Yes.

12 Q. Then we've got a column that says "filter," and what's
13 going on in that column?

14 A. Sure. So on the case report form where these events are
15 reported to the sponsor, there is a question that asks the
16 physician to give his interpretation or her interpretation as
17 to whether or not that event had something to do with the
18 device, in this case the filter. So it would say "not related"
19 or "related."

01:19PM

20 MR. ROGERS: Scott, if you don't mind could you pull
21 out the section on Patient 06-14, please. And how about pull
22 out everything down through Number 9, if you would, all
23 together.

01:19PM

24 BY MR. ROGERS:

25 Q. Can you see that, Mr. Van Vleet?

01:20PM

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1 A. Yes.

2 Q. And so on that far column, it says 06-14. Are all these
3 adverse events, do they all relate to one patient?

4 A. They are. There are nine of them total.

5 Q. And how many events -- I'm sorry. You just said it. This
6 patient had nine events?

01:20PM

7 A. Yes.

8 Q. Let's kind of walk through those if you would. The first
9 one says "hepatotoxicity." What is that?

10 A. That means basically poisoning of the liver, essentially.
11 And it looks here that they were taking Dilantin, which is a
12 medication for seizure purposes, and they may have reached some
13 toxic levels of that.

01:20PM

14 Q. Was that coded as being related to the filter?

15 A. It was coded as not related.

01:20PM

16 Q. And the second issue that this patient had is something
17 called atrial flutter. What is that?

18 A. That is a quivering or vibration of the heart. It's very
19 common in people over 65, 70 years of age.

20 Q. Was that coded as being related to the filter?

01:21PM

21 A. It was coded as not related.

22 Q. And next on the third adverse event is dysphasia. What is
23 that?

24 A. It is the -- not inability, but the loss of desire to eat,
25 essentially.

01:21PM

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1 Q. And was that coded as being related to the filter?

2 A. Not related.

3 Q. And just to kind of move this on, Mr. Van Vleet, looks like
4 we've got sinusitis, esophagitis, hiatal hernia, diarrhea, oral
5 candidiasis -- I'm sure I'm not saying that right -- and rash.

01:21PM

6 Do you see all those?

7 A. I do.

8 Q. Were any of those coded as being related to the filter?

9 A. They were all coded as not related.

10 Q. And then looking more specifically as the more detailed
11 description of those events, can you provide the jury some
12 additional information about those things?

01:21PM

13 A. Yeah. So Number 4, sinusitis, it would be an infection of
14 the sinuses. Esophagitis is an irritation of your swallowing
15 portion of your throat. Hiatal hernia is part of your
16 intestine, sometimes can protrude through tears in your
17 abdominal cavity. Diarrhea is self-explanatory. Oral
18 candidiasis is a yeast infection of the mouth. And rash is a
19 fungal rash growing in axillae. Axillae is your armpit.

01:22PM

20 Q. Were all of these adverse events reported as being adverse
21 events in the EVEREST study?

01:22PM

22 A. They were.

23 Q. Mr. Van Vleet, let's switch over to a different page and go
24 to Page 57, please.

25 MR. ROGERS: And can you pull out the information for

01:22PM

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1 the patient, that very first patient at the top. Thank you.

2 BY MR. ROGERS:

3 Q. And Mr. Van Vleet, tell us what's occurring in this
4 particular row.

5 A. I need to read it for a second.

01:23PM

6 Okay. This was a report of a perforation or other
7 acute or chronic damage of the inferior vena cava, which is the
8 big vessel that the filter is placed in. So the filter had
9 perforated or damaged the IVC or the inferior vena cava.

10 Q. Was that an adverse event that was reported as being
11 related to the filter?

01:23PM

12 A. Yes. Definitely.

13 Q. Does it specifically say "definitely" there?

14 A. It says "definitely."

15 Q. Mr. Van Vleet, we have seen some examples of the way these
16 adverse events are reported. And the jury has also heard that
17 the adverse event rate for the EVEREST study was over 50
18 percent. And would that include all of these adverse events?

01:23PM

19 A. Yes.

20 Q. And would it include the adverse events that are not
21 related to the filter or that were coded as not related to the
22 filter?

01:24PM

23 A. Yes.

24 MR. ROGERS: We can bring that down. And Let's call
25 up Exhibit 5335, please.

01:24PM

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1 And, Your Honor, this has been admitted. May we
2 publish?

3 THE COURT: Yes.

4 BY MR. ROGERS:

5 Q. Mr. Van Vleet, can you tell the jury, please, what this is?

01:24PM

6 A. This is another annual progress report on the clinical
7 trial, the investigational device exemption study.

8 Q. So let's go to Page 18 of that document.

9 And Mr. Van Vleet, at the bottom of the page there,
10 what did Bard tell FDA about the complications observed during
11 the EVEREST study?

01:24PM

12 A. Sure. I will read from the report: In total, there were
13 10 filter migrations greater than two centimeters reported with
14 a mean follow-up of five months. These migration were all
15 caudal in direction between 2.0 and 4.1 centimeters and without
16 clinical sequelae, which means any further complication.

01:24PM

17 No subject with filter migration was found to have a
18 subsequent pulmonary embolus and no filter embolized. PE,
19 pulmonary embolus, is a blood clot to the lungs. Of these 10
20 migrated filters, five were successfully retrieved; three were
21 left in place without attempted retrieval; and two remained in
22 place after a failed retrieval procedure. A total of six
23 subjects had expired during the course of the EVEREST study.
24 The following is a summary for two subjects.

01:25PM

25 Do you want me to continue reading?

01:25PM

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1 Q. No. That's okay. You can take that down.

2 Did Bard have subsequent communications with FDA about
3 caudal migration?

4 A. Yes, it did.

5 MR. ROGERS: Can we pull up Exhibit 5334, please.

01:25PM

6 And, Your Honor, may we publish? This has been
7 admitted.

8 THE COURT: You may.

9 BY MR. ROGERS:

10 Q. Mr. Van Vleet, how about tell the jury what this is,
11 please.

01:26PM

12 A. This is a letter from the FDA to the regulatory
13 correspondent, a Bard employee, asking them questions about the
14 application that they were reviewing, the 510(k).

15 Q. Let's go to Question 3 on the following page.

01:26PM

16 MR. ROGERS: And could you pull that out, please.

17 BY MR. ROGERS:

18 Q. And so Mr. Van Vleet, what did FDA want to know from Bard
19 about the caudal migration information?

20 A. Sure. They said that we have reported that there have been
21 10 migrations in the 100-patient study. This equates to an
22 incidence of migration of 10 percent. Please explain why this
23 rate of device migration the clinically acceptable. In
24 addition, please provide a comparison of the approximate
25 migration rates of the currently marketed Recovery and G2

01:26PM

01:26PM

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1 Filter devices based on your clinical experience as compared to
2 the investigational Recovery Filter studied in the EVEREST
3 trial.

4 Q. Did Bard respond to this letter?

5 A. Yes.

01:27PM

6 MR. ROGERS: Can we pull up Exhibit 5336?

7 And, Your Honor, may we publish? It's been admitted.

8 THE COURT: Yes.

9 BY MR. ROGERS:

10 Q. Mr. Van Vleet, I think we need to probably go to Page 13 of
11 the letter. And do you see the portion there about question
12 Number 3?

01:27PM

13 A. Yes.

14 Q. And what did Bard tell the FDA in regard to caudal
15 migration?

01:27PM

16 A. Do you want me to read it or paraphrase?

17 Q. You can paraphrase.

18 A. Okay. So they had -- the question originally was 10
19 patients out of the 100-patient study were reported to have
20 some level of migration, which would be 10 percent. And the
21 FDA said, please help us understand why this is clinically
22 acceptable. So the first thing that we did in the response is
23 correct that, because while there were 100 patients in the
24 study, I believe there were only images available for 82. So
25 10 divided by 82 is actually 12.2 percent.

01:27PM

01:28PM

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1 So we revised the percentage to show what we knew to
2 be true. And then it talks about the levels of migration and
3 the distances that it migrated.

4 Q. During the course of your working with the EVEREST study,
5 to your knowledge, were all the adverse events that occurred
6 during that study reported to the FDA?

01:28PM

7 A. Yes.

8 Q. Let's move on to the next document, which is Exhibit 5340.

9 MR. ROGERS: And, Your Honor, may we publish? This is
10 already in evidence.

01:28PM

11 THE COURT: Yes, you may.

12 BY MR. ROGERS:

13 Q. Mr. Van Vleet, what is this document?

14 A. This is the application to the FDA for request to clear the
15 G2 Filter system. It's a traditional 510(k).

01:28PM

16 Q. And was this submitted to the FDA after the EVEREST study
17 was completed?

18 A. Yes.

19 Q. And about how big is this document, Mr. Van Vleet, if you
20 know?

01:29PM

21 A. Well, it would be much larger than a typical 510(k) because
22 it would include the entire clinical study report and patient
23 line listings. This is probably 1500 pages, perhaps, 1500.

24 Q. Let's go over to Page 339 of the document.

25 Mr. Van Vleet, tell us what this is, please.

01:29PM

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1 A. This is actually the title page for the final study report.

2 Q. So was the final study report provided to FDA in its
3 entirety?

4 A. Yes.

5 MR. ROGERS: And can we go over to Page 406?

01:29PM

6 And pull out the table there.

7 BY MR. ROGERS:

8 Q. So what is this information?

9 A. Sure. This is a listing of filter-related device
10 observations as defined by the American College of Radiology
11 and the Society For Interventional Radiology. It lists five
12 different types. And then it has a miscellaneous column. And
13 it compares the data that were collected in the EVEREST study
14 with the classifications that both ACR and SIR have and divides
15 them into major and minor complications.

01:29PM

01:30PM

16 Q. And according to this table, how many patients in the
17 EVEREST study experienced a fracture?

18 A. One.

19 Q. Do you know if that patient was symptomatic or
20 asymptomatic?

01:30PM

21 A. I believe that patient was no symptoms.

22 MR. ROGERS: Let's go over to Page 408. And can we
23 pull out this chart, please?

24 BY MR. ROGERS:

25 Q. So Mr. Van Vleet, can you tell us what this chart is?

01:30PM

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1 A. This is, again, device observations compared to what the
2 Society For Interventional Radiology standards are. It
3 includes migration greater than two centimeters; embolization
4 which basically means when the filter, or part of the filter,
5 moves with the blood flow; filter fracture; and filter
6 penetration.

01:31PM

7 Q. So in regard to filter fracture, how did that rate that was
8 reported in EVEREST compare to the SIR rate?

9 A. So the one patient presumably divided by the 82 patients
10 that had evaluable images equals 1.2 percent, and SIRs range
11 that they have published that would be expectable in these
12 populations is somewhere between 2 and 10 percent.

01:31PM

13 Q. Let's go on to Page 797, please.

14 MR. ROGERS: And would you mind pulling that out, the
15 table?

01:31PM

16 BY MR. ROGERS:

17 Q. And Mr. Van Vleet, can you describe for the jury, please,
18 what this table represents?

19 A. Sure. This is a listing or a summary of all of the
20 recorded movements in the EVEREST study in any patient.

01:32PM

21 Q. When you say "recorded movements" what does that mean?

22 A. So there is an independent evaluator that looks at images
23 and makes the determination if the device has moved since its
24 original implantation.

25 Q. Down at the bottom it says: Movement greater than two

01:32PM

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1 centimeters. Do you see that?

2 A. Yes.

3 Q. So was there a particular definition of what migration was
4 defined at for this study?

5 A. Yes. It was based on the SIR recommendation that a
6 movement of greater than two centimeters be considered to be
7 actually significant.

01:32PM

8 Q. And the other ones that are above movement greater than two
9 centimeters, those are all less than two centimeters of
10 movement?

01:32PM

11 A. Yes. Those are all expressed in millimeters.

12 Q. Was all this information provided to FDA?

13 A. Yes.

14 Q. Mr. Van Vleet, were the results of the EVEREST study
15 published in the medical literature?

01:33PM

16 A. Yes, they were.

17 Q. And can we pull up Exhibit 6892.

18 And do you have that exhibit on your screen?

19 A. I do.

20 Q. And tell the jury what it is, please.

01:33PM

21 A. Sure. It's -- I will read the title of the paper, which is
22 the Technical Success and Safety of Retrieval of the G2 Filter
23 and a Prospective Multicenter Study. And this was published in
24 Journal of Vascular and Interventional Radiology which is the
25 journal for the Society of Interventional Radiology in 2009.

01:33PM

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1 MR. ROGERS: Your Honor, at this time I move Exhibit
2 6892 into evidence.

3 MR. CLARK: Your Honor, I think he's touched the basis
4 for 803.18 but nothing more.

5 THE COURT: Your response?

01:33PM

6 MR. ROGERS: Your Honor, I'm admitting it not for the
7 truth of the matter but notice to the medical community and the
8 information that was provided about the G2 Filter and the
9 results of this study within the greater community for doctors
10 who used these types of devices.

01:34PM

11 THE COURT: Counsel, let's talk about that for a
12 minute.

13 If you want to stand up, Ladies and Gentlemen.

14 (Discussion was had at sidebar out of the hearing of
15 the jury:)

01:34PM

16 THE COURT: Why is notice to the medical community
17 about the G2 relevant?

18 MR. ROGERS: Well, Your Honor, the jury's heard a lot
19 of evidence how the Eclipse is nothing but the G2 that's been
20 electropolished. And, of course, the plaintiff's contention in
21 this case is the electropolish really didn't do anything. So I
22 think that we would like to be able to show, you know, what the
23 information in the medical literature was about the G2.

01:34PM

24 THE COURT: Well, but that sounds to me like it's for
25 the truth of the matter asserted. You would like to show what

01:34PM

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1 the medical literature said about the complication rates on the
2 G2.

3 MR. ROGERS: Let me rephrase, Your Honor. What was
4 the information that was available to the doctors.

5 THE COURT: My question is: Why is that relevant?
6 Why is notice to doctors about the G2 independent of the truth
7 of the matter asserted relevant in this case?

01:35PM

8 MR. ROGERS: Your Honor, I don't have a better answer
9 so if that's where we are, you want me to move on?

10 THE COURT: No. My ruling, then, is this really is
11 being offered for the truth of the matter asserted. So I'm
12 going to sustain the objection to admission but you can use it
13 under 803.18. I think you didn't have an objection to that.

01:35PM

14 MR. CLARK: I agree with that.

15 THE COURT: So you can read portions in but we can't
16 admit the document.

01:35PM

17 MR. ROGERS: Sure. Thank you, Your Honor.

18 (In open court.)

19 THE COURT: Thank you, Ladies and Gentlemen.

20 BY MR. ROGERS:

01:35PM

21 Q. Mr. Van Vleet, I'm going to get you to provide the jury
22 some information that's contained in this document.

23 Do you see it?

24 A. Yes.

25 Q. And the results section that is there in front of you, can

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1 you tell the jury if that matches the information that was in
2 the clinical study that was provided to FDA?

3 A. Yes.

4 Q. And so does this article report information from the
5 EVEREST study about fracture, migration, penetration, and tilt?

01:36PM

6 A. It does.

7 Q. So is that information available in the medical literature?

8 A. Yes.

9 MR. ROGERS: Let's move on to Exhibit 5339, please.

10 And, Your Honor, may I publish? It's in evidence.

01:36PM

11 THE COURT: Is that 539?

12 MR. ROGERS: 5339.

13 THE COURTROOM DEPUTY: Yes, it's in.

14 THE COURT: Yes. You may publish.

15 BY MR. ROGERS:

01:36PM

16 Q. Mr. Van Vleet, what is this document?

17 A. This is a letter from the FDA to the regulatory
18 correspondent at Bard informing them that the FDA has
19 considered the device in question to be substantially
20 equivalent, or in other words, they have cleared the device for
21 commercial distribution.

01:37PM

22 Q. And would that be commercial distribution with a labeled
23 indication as a retrievable filter?

24 A. Yes.

25 Q. So let's move forward, Mr. Van Vleet, to some additional

01:37PM

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1 documents.

2 MR. ROGERS: And how about pull up 5354.

3 And, Your Honor, this document is already in evidence.

4 May we publish?

5 THE COURT: Yes.

01:37PM

6 BY MR. ROGERS:

7 Q. Mr. Van Vleet, can you describe for the jury what this
8 document is?

9 A. Yeah. It's the cover page from another application to FDA.
10 This would be a special 510(k).

01:37PM

11 Q. And what in this particular 510(k) was FDA asking -- or
12 excuse me -- was Bard asking FDA to clear?

13 A. I have to -- oh. Change, I believe, in the delivery
14 system.

15 Q. And let's go to Exhibit 5353.

01:37PM

16 Your Honor, may we publish? This is in evidence.

17 THE COURT: You may.

18 BY MR. ROGERS:

19 Q. Mr. Van Vleet, what is this document?

20 A. This appears to be the clearance letter from FDA clearing
21 the previous application.

01:38PM

22 Q. And would this be the third time that the FDA has cleared a
23 product that's related to the G2 Filter?

24 A. I believe so.

25 MR. ROGERS: How about let's move to Exhibit 5361.

01:38PM

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1 And, Your Honor, may we publish? This is in evidence.

2 THE COURT: You may.

3 BY MR. ROGERS:

4 Q. Mr. Van Vleet, what's this document?

5 A. It is another submission to the FDA, a special 510(k)
6 submission for the G2 Filter system and some modification to
7 the delivery kit.

01:38PM

8 MR. ROGERS: And may we pull up 5362.

9 And, Your Honor, may we publish this which is also in
10 evidence?

01:39PM

11 THE COURT: Yes.

12 BY MR. ROGERS:

13 Q. And Mr. Van Vleet, was the application that we saw just a
14 moment ago, was that also cleared by FDA?

15 A. Yes. This is the clearance letter clearing that
16 application.

01:39PM

17 Q. And was that the fourth clearance that the FDA had done on
18 the G2 Filter?

19 A. I believe so.

20 Q. All right. Mr. Van Vleet, how about tell us what the G2
21 Express Filter is.

01:39PM

22 A. The G2 Express was the inclusion of a hook at the apex of
23 the filter to enable it to be retrieved with a snare.

24 Q. Did Bard submit a 510(k) application to the FDA for the G2
25 Express for clearance?

01:39PM

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1 A. Yes.

2 MR. ROGERS: Can we pull up Exhibit 5373.

3 And, Your Honor, may we publish? That's also
4 admitted.

5 THE COURT: Yes.

01:40PM

6 BY MR. ROGERS:

7 Q. Mr. Van Vleet, is this the 510(k) application?

8 A. This is the 510(k) requesting clearance for the addition of
9 a hook onto the apex.

10 Q. Was this submission ultimately cleared?

01:40PM

11 A. Yes.

12 MR. ROGERS: And can we pull up 5368. Your Honor, may
13 we publish?

14 THE COURT: Yes.

15 BY MR. ROGERS:

01:40PM

16 Q. Mr. Van Vleet, was this the letter from FDA clearing that
17 application for the G2 Express?

18 A. Yes, it is.

19 MR. ROGERS: How about let's go to 5379.

20 And, Your Honor, may we publish? This is in evidence.

01:40PM

21 THE COURT: Yes.

22 BY MR. ROGERS:

23 Q. Mr. Van Vleet, is this another application for the G2
24 Express?

25 A. Yes, it is.

01:40PM

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1 Q. And what is this for?

2 A. This is, I believe, for a modification of the delivery
3 system G2 Express.

4 MR. ROGERS: And can we go to Exhibit 5376?

5 Your Honor, may we publish? It's in evidence.

01:41PM

6 THE COURT: Yes.

7 BY MR. ROGERS:

8 Q. Mr. Van Vleet, was this particular application cleared by
9 the FDA?

10 A. Yes. This is the clearance letter from FDA.

01:41PM

11 Q. Was that the sixth clearance we have seen for the G2 line
12 of filters?

13 A. Yes.

14 Q. Okay. Let's turn our attention to the Eclipse Filter, if
15 you would, Mr. Van Vleet.

01:41PM

16 Were you personally involved with the regulatory
17 filings for the Eclipse Filter?

18 A. I was.

19 Q. So before Bard ever submitted a clearance application to
20 FDA for the Eclipse, did you have communications with the FDA?

01:41PM

21 A. Yes.

22 Q. And did you have communications with FDA about the Eclipse
23 Filter?

24 A. Yes.

25 Q. And can we pull up Exhibit 5593, please.

01:41PM

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1 Mr. Van Vleet, do you have that on your screen?

2 A. Yes.

3 Q. Can you tell us what this is, please?

4 A. This is meeting minutes from a meeting held with our
5 reviewer at FDA. After the meetings are concluded FDA requests
6 that we submit to them a copy of our meeting minutes and then
7 they usually have some editorial comments and change some
8 things. And once they are agreed upon they are filed.

01:42PM

9 Q. In the second paragraph there's something referred to there
10 called G2 Platinum. Do you see that?

01:42PM

11 A. Uh-huh.

12 Q. Can you tell the jury what G2 Platinum is?

13 A. So I believe G2 Platinum was a project that was being
14 undertaken to terminally electropolish or provide a more
15 consistent surface finish on the G2 family of products.

01:42PM

16 Q. And did the G2 Platinum project make it anywhere, or did it
17 kind of get scrapped?

18 A. No. It ended up being scrapped because it was not feasible
19 to electropolish it given some of the constructs of it.

20 Q. So if we go to Page 2 of this document, and up at the top
21 there in that paragraph, do you see where it references caudal
22 anchors?

01:42PM

23 A. Yes.

24 Q. And so what was being relayed to FDA about caudal anchors?

25 A. So simply that this would be the next upcoming project that

01:43PM

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1 they would be seeing. We try always to provide FDA kind of a
2 sense of the timing and what -- for them to be able to manage
3 their workload.

4 Q. And did the caudal anchors ultimately get added to the Bard
5 filter?

01:43PM

6 A. Yes.

7 Q. Was that in a filter called the Meridian Filter?

8 A. Yes.

9 Q. Let's look down at the bottom of this document, please.

10 Mr. Van Vleet, do you see where it references laser cut filter
11 with caudal anchors?

01:43PM

12 A. Yes.

13 Q. And what does that mean, laser cut?

14 A. So it would be a product that is cut out of a tube, in this
15 case Nitinol, nickel titanium, via laser, basically carved
16 through a laser cut, single construct. One solid state.

01:44PM

17 Q. And did Bard ultimately introduce into the marketplace a
18 laser cut filter?

19 A. Yes.

20 Q. And which filter is that?

01:44PM

21 A. That's the Denali Filter.

22 Q. Is that the filter that's on the market currently?

23 A. Yes, it is.

24 Q. And so is this information about projects involving caudal
25 anchors and potentially laser cutting a filter, was it all

01:44PM

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1 provided to FDA before the application for the Eclipse Filter
2 was cleared?

3 A. Yes.

4 Q. Let's pull up Exhibit 5612, please.

5 Mr. Van Vleet, do you have that on your screen?

01:44PM

6 A. I do.

7 Q. Can you tell the jury, please, what this document is?

8 A. This is, again, meeting minutes. We called them FDA
9 contact reports.

10 Q. Does this reflect additional communications between Bard
11 and the FDA regarding the Eclipse project?

01:45PM

12 A. Yes, it does.

13 Q. So let's move on to Exhibit 5272.

14 MR. ROGERS: Your Honor, may we publish? This is in
15 evidence.

01:45PM

16 THE COURT: Yes.

17 BY MR. ROGERS:

18 Q. Mr. Van Vleet, can you tell the jury what this is?

19 A. Sure. This is the cover page for a special 510(k)
20 submission requesting FDA to clear the Eclipse Filter system.

01:45PM

21 Q. And can you go to Page 2 of the document.

22 And can you just describe generally for the jury what
23 types of information was provided about the Eclipse Filter to
24 FDA in this application?

25 A. So this would include the summary of all of the testing,

01:45PM

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1 identification of the materials, any change to a process of
2 manufacturing, just a comprehensive listing of anything that
3 would have changed from the predicate device.

4 Q. And would this application also include a draft IFU, or
5 Instructions For Use, for the Eclipse?

01:46PM

6 A. Yes.

7 Q. And to your knowledge, did FDA ask for additional or
8 different warnings regarding the Eclipse IFU?

9 A. I don't believe they did.

10 Q. Can you pull up Exhibit 5273, please.

01:46PM

11 MR. ROGERS: Your Honor, may we publish? This is in
12 evidence.

13 THE COURT: Yes.

14 BY MR. ROGERS:

15 Q. Mr. Van Vleet, what is this?

01:46PM

16 A. This is the letter from the FDA clearing the Eclipse 510(k)
17 submission.

18 Q. And once Bard received this letter from FDA clearing the
19 Eclipse Filter, was that sort of the green light where Bard
20 could start to market the device?

01:46PM

21 A. Yes.

22 Q. And let's move on to -- let's see. Well, let me ask you a
23 couple questions first.

24 Did Bard submit an additional 510(k) to FDA regarding
25 the Eclipse Filter?

01:46PM

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1 A. Yes. I believe there was a follow-up submission including
2 a patient brochure and an implant card.

3 Q. Would you pull up Exhibit 5586.

4 MR. ROGERS: And, Your Honor, may we publish? This is
5 in evidence.

01:47PM

6 THE COURT: Yes.

7 BY MR. ROGERS:

8 Q. And Mr. Van Vleet, is this the second application that
9 relates to the Eclipse Filter?

10 A. Yes.

01:47PM

11 Q. And tell us, if you would, what was the purpose of this
12 second submission?

13 A. I would have to take a look at it, but I think that was
14 adding the patient brochure and the implant card.

15 Q. Let's go to Page 78 of the document.

01:47PM

16 A. Yes.

17 Q. And if you look through 78, and -- well, yeah.

18 MR. ROGERS: Are you going to make that bigger there
19 Scott?

20 Thank you.

01:48PM

21 BY MR. ROGERS:

22 Q. So Mr. Van Vleet, tell the jury what this is.

23 A. This is an informational card for patients receiving the
24 Eclipse Filter.

25 Q. And can you go to the next page?

01:48PM

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1 Was this also part of that same card?

2 A. Yeah. It's a tri-fold or quad-fold brochure. It's about
3 this shape and it all folds up against itself.

4 Q. And how was this card and other information supposed to be
5 delivered with the Eclipse Filter?

01:48PM

6 A. It was kangaroo pouched on the outside of the package as an
7 added piece of information.

8 Q. And what do you mean be by kangaroo pouched?

9 A. So it was included in a pouch, or an envelope, a clear
10 plastic envelope stuck to the outside of the package so the
11 physician and the staff would know that it needs to be
12 associated with that package.

01:48PM

13 Q. So it's literally on the external part of the box that the
14 delivery system comes in?

15 A. Correct.

01:49PM

16 Q. Can we go to Exhibit 5587.

17 MR. ROGERS: And, Your Honor, this is in evidence.
18 May we publish?

19 THE COURT: Yes.

20 BY MR. ROGERS:

01:49PM

21 Q. And Mr. Van Vleet, can you tell us what this letter is?

22 A. This was a response to the 510(k) for the inclusion of the
23 patient brochure and implant card. And it's what we call an
24 additional inquiry letter so FDA had questions about the
25 submission.

01:49PM

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1 Q. So what was the question that FDA was raising?

2 A. Number one talks about in the patient brochure, the
3 question is: When can the filter be removed? And the
4 statement that was proposed initially was: The Eclipse Vena
5 Cava Filter does not have a time in which it must be removed. 01:50PM

6 So FDA was questioning that because they felt that Bard had not
7 provided clinical data to support the statement. And then it
8 pulled out the data that was submitted from the EVEREST study
9 on 58 patients with a mean retrieval time of 140 days. And
10 that was observational data. I'm trying to read their mind at 01:50PM
11 this point in time.

12 But they felt that that was not sufficient to
13 substantiate the statement that the filter does not have a time
14 limit for retrieval.

15 Q. And did Bard respond to this letter? 01:50PM

16 A. Yes.

17 MR. ROGERS: Could be pull up Exhibit 5488?

18 Your Honor, may we publish?

19 THE COURT: Yes.

20 BY MR. ROGERS: 01:50PM

21 Q. And Mr. Van Vleet, is this Bard's response to FDA?

22 A. Yes.

23 Q. Can we go to Page 6 of that document.

24 MR. ROGERS: And can we pull out the section about the
25 patient brochure up at the top? Thank you. 01:51PM

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1 BY MR. ROGERS:

2 Q. And so Mr. Van Vleet, what was -- well, this is the actual
3 question from FDA, correct?

4 A. Correct.

5 Q. And so let's look down below that, please. And so what did
6 Bard respond to as far as this question is concerned?

7 A. So the patient brochure was revised, and the section on
8 when can the filter be removed was actually taken out of the
9 patient brochure.

01:51PM

10 Q. And was the patient brochure application cleared by FDA?

01:51PM

11 A. Yes.

12 Q. And can we pull up Exhibit 5589.

13 MR. ROGERS: Your Honor, may we publish? This is in
14 evidence.

15 THE COURT: Yes.

01:52PM

16 BY MR. ROGERS:

17 Q. Mr. Van Vleet, is this the letter from FDA clearing the
18 510(k) application for the patient brochure?

19 A. Yes.

20 Q. Can we pull up now Exhibit 8362.

01:52PM

21 And Mr. Van Vleet, can you tell us what this is,
22 please?

23 A. That is a copy of the patient brochure for the Eclipse Vena
24 Cava Filter.

25 Q. And is this the version that FDA cleared?

01:52PM

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1 A. I believe so. There's usually a little code number at the
2 bottom that tells us it's the final version.

3 Q. And Mr. Van Vleet, we can flip to the back page if you want
4 to see it. I'm not sure if it's there.

5 MR. ROGERS: Is there a second page there, Scott? 01:52PM

6 THE WITNESS: Yes. I believe this is the final.

7 MR. ROGERS: And Your Honor, at this time I move
8 Exhibit 8362 into evidence.

9 MR. CLARK: Objection, relevance. No evidence that
10 Mrs. Jones received this brochure. 01:53PM

11 THE COURT: Overruled. 8362 is admitted.

12 MR. ROGERS: Can we go back to the first page,
13 please.

14 BY MR. ROGERS:

15 Q. And before we actually get into the actual language of this 01:53PM
16 brochure, Mr. Van Vleet, why did Bard decide to create this
17 patient brochure for the Eclipse Filter?

18 A. So upon conversations with FDA we were asked to create this
19 for informing the patients. And the requirement, generally
20 speaking, for many if not most implantable devices is that 01:53PM
21 there is a specific brochure that's targeted toward the patient
22 that provides information about the case, the device, any
23 potential risks with the device, and it has to be written at a
24 level that a non-medical person can understand.

25 Q. And was there any intention with this brochure to do 01:54PM

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1 something in order to -- that would change the relationship
2 between the patient and the doctor who may implant one of these
3 devices?

4 A. No.

5 Q. Okay. So let's take a look at, I guess this generally. So 01:54PM
6 on this first page is there some general information about
7 pulmonary embolism?

8 A. Yes.

9 Q. Are there also information about alternative treatments for
10 pulmonary embolism besides an IVC filter? 01:54PM

11 A. Yes.

12 Q. In the middle there, where there's a question, what is a
13 vena cava filter? Do you see that?

14 A. Yes.

15 Q. Does that provide the patient some information and a 01:54PM
16 picture of a vena cava filter?

17 A. Yes, it does.

18 Q. And then over on the right-hand side, is there information
19 about the implant procedure itself?

20 A. There is. 01:54PM

21 Q. And can we go to the next page, please.

22 And in this portion, starting, I guess, over on the
23 left-hand side, that first column of writing where it says
24 "after the procedure," do you see that?

25 A. Yes. 01:55PM

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1 Q. And does this provide some information about what the
2 patient may expect?

3 A. Yes, it does.

4 Q. And then it looks like in the middle column there is a
5 column there that says, "What are the risks associated with
6 implantable filters." Do you see that?

01:55PM

7 A. Yes.

8 MR. ROGERS: And let's go down to the section -- just
9 pull the whole thing out, if you would, please, Scott. Thank
10 you.

01:55PM

11 Looking at the bullet point that's the next to the
12 last one on the page, can you pull that out, please?

13 BY MR. ROGERS:

14 Q. Mr. Van Vleet, what does that paragraph state?

15 A. Sure. I will just read it: The entire filter or pieces of
16 the filter may break loose and travel to the heart or lungs
17 causing injury or death. You may need to have additional
18 surgery to retrieve the filter or pieces if they break loose.

01:55PM

19 Q. And what was the reason to include that information in the
20 brochure for the patient?

01:56PM

21 A. Well, it's, number one, fair balance. You can't simply say
22 anything that's just good about a device. You have to also be
23 very transparent about any risks the device had. And these
24 complications are events that have been known either from the
25 literature to occur in cases where people use IVC filters or if

01:56PM

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1 there were specific studies on the filter they would be derived
2 from the studies, adverse event listing of the studies.

3 MR. ROGERS: Scott, would you take that down. Pull
4 out the section that's on the top right, "Does the filter have
5 to be removed."

01:57PM

6 BY MR. ROGERS:

7 Q. And Mr. Van Vleet, is this the section we were discussing
8 earlier where there was a back-and-forth with FDA about what
9 sort of information should be provided in regard to the answer
10 to this question?

01:57PM

11 A. Yes.

12 Q. And does this reflect the change that FDA wanted to make?

13 A. Yes.

14 Q. So what's the information that was ultimately provided to
15 the patient in this brochure about does the filter have to be
16 removed?

01:57PM

17 A. The answer that is provided is: No, the Eclipse Vena Cava
18 Filter is designed to be a permanent implant and does not have
19 to be removed, repositioned, or replaced. However, in the
20 cases where the risk for pulmonary embolism is temporary, your
21 physician may choose to remove the filter. You should discuss
22 filter removal with your physician. There's a typo.

01:57PM

23 Q. Thank you, Mr. Van Vleet.

24 MR. ROGERS: You can take that down. You can take the
25 whole thing down.

01:57PM

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1 BY MR. ROGERS:

2 Q. Let's talk for a little bit about the IFU that was provided
3 with the Eclipse Filter. And how does the IFU differ from what
4 we just looked at, which was the patient brochure?

5 A. The IFU is targeted toward the physician. So the way the
6 description is written would be more at a higher technical
7 medical level. It also is much more comprehensive. And there
8 are specific sections to the Instructions For Use that are
9 required by FDA. So it's essentially a negotiation or a
10 conversation with FDA, and FDA has the ultimate authority on
11 what must be included in an IFU.

01:58PM

01:58PM

12 Q. What was your role in the preparation of the IFU that
13 accompanied the Eclipse Filter?

14 A. I would have to review and approve anything going to the
15 FDA.

01:58PM

16 MR. ROGERS: And can we pull up Exhibit 8235?

17 And, Your Honor, may we publish this? It's in
18 evidence.

19 THE COURT: Yes.

20 BY MR. ROGERS:

01:59PM

21 Q. Mr. Van Vleet, is this a copy of the IFU, at least a cover
22 page for the IFU?

23 A. For the Eclipse Vena Cava Filter, yes.

24 MR. ROGERS: Let's go to Page 4, please. Scott, would
25 you pull out the section there that -- Yeah. Part E. Do you

01:59PM

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1 see that?

2 BY MR. ROGERS:

3 Q. Mr. Van Vleet, what is this section?

4 A. This is the warning section which is a required section in
5 any IFU. And it includes a listing of any relevant event or
6 any relevant knowledge about the performance of the device that
7 the physician should know.

01:59PM

8 Q. And can we pull out Number 11, please.

9 And Mr. Van Vleet, was this -- what's up on the screen
10 now, is that in the warnings portion of the IFU?

01:59PM

11 A. It is.

12 Q. Would you read that for the jury, please?

13 A. Filter fractures are a known complication of vena cava
14 filters. There have been some reports of serious pulmonary and
15 cardiac complications with vena cava filters requiring the
16 retrieval of the fragment utilizing endovascular and/or
17 surgical techniques.

02:00PM

18 Q. What was the purpose of including this information in the
19 IFU?

20 A. It was one of the known complications of IVC filters. And
21 part of the requirements for the Instructions For Use is that
22 all known risks surrounding the use of a device be included.

02:00PM

23 MR. ROGERS: And Scott, would you take that down and
24 pull out the next section, Number 12, please.

25 BY MR. ROGERS:

02:00PM

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1 Q. Mr. Van Vleet, would you read Number 12 for the jury?

2 A. Movement migration or tilt of the filter are known
3 complications of vena cava filters. Migration of the filters
4 to the heart or lungs has been reported. There have also been
5 reports of caudal migration of the filter. Migration may be
6 caused by placement in IVCs with diameter exceeding the
7 appropriate labeled dimension specified in this IFU. Migration
8 may also be caused by proper deployment, deployment into clots,
9 and/or dislodgement due to the large clot burdens.

02:01PM

10 Q. What was the purpose of including this information in the
11 warning section of the IFU?

02:01PM

12 A. Again, just a continuing need to make sure that any known
13 complications for these types of devices are being
14 appropriately represented to the physicians using them.

15 MR. ROGERS: Scott, can you take that down and go to
16 the next page. And up at the top, can you pull out the Part G?
17 Section G? Thank you.

02:01PM

18 BY MR. ROGERS:

19 Q. Mr. Van Vleet, do you see up at the top where it says
20 "potential complications"?

02:01PM

21 A. Yes.

22 Q. How does this section in an IFU about complications differ
23 than a section about warnings?

24 A. It's more detailed, I think, and it also would include any
25 observed complication, again, combed from the literature but

02:02PM

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1 it's just kind of a listing of each individual complication.

2 Q. And do the first bullets --

3 MR. ROGERS: Can you pull those out, please, Scott.

4 BY MR. ROGERS:

5 Q. Do those first two bullets that are there, do they match
6 what had been provided in the warning section?

02:02PM

7 A. Yes. I believe it's the same warning.

8 Q. Okay. So let's go down to the next bullet below those two.

9 And Mr. Van Vleet, can you read that for the jury,
10 please?

02:02PM

11 A. Perforation or other acute or chronic damage of the IVC
12 wall.

13 MR. ROGERS: And how about scroll on down a little
14 ways below, little more. And down right, it's just coming up
15 there. And can you highlight that bullet?

02:03PM

16 BY MR. ROGERS:

17 Q. And Mr. Van Vleet, what does that say?

18 A. Filter tilt.

19 Q. And so were perforation and tilt also provided as potential
20 complications in the information in the IFU about the Eclipse
21 Filter?

02:03PM

22 A. Yes, they were.

23 MR. ROGERS: And let's go on down to Figure 6. You
24 pull that down. This is the clinical studies section.

25 Next page. Here we go.

02:03PM

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1 BY MR. ROGERS:

2 Q. Do you see that there where it says "clinical experience"?

3 Mr. Van Vleet, describe for us, if you would, what is
4 this portion of the IFU?

5 A. So in the case that devices have had clinical data
6 submitted as part of the application, there's a required
7 summary of the overall results of whatever study was performed.
8 And this is a summary of the clinical data.

02:03PM

9 Q. And was this the clinical data for the EVEREST study?

10 A. Yes.

02:04PM

11 MR. ROGERS: And can you scroll down a little bit,
12 please, Scott. And so in this section here that starts right
13 above the bolded language, can you pull that out, that
14 sentence, where it begins, "asymptomatic complications."

15 BY MR. ROGERS:

02:04PM

16 Q. And Mr. Van Vleet, what is this?

17 A. This is a summary of complications that didn't have any
18 symptoms.

19 Q. And was this information provided in every IFU that
20 accompanied the Eclipse Filter?

02:04PM

21 A. Yes.

22 MR. ROGERS: All right. You can pull that down.

23 BY MR. ROGERS:

24 Q. Mr. Van Vleet, I want to kind of change our attention and
25 talk some more about sort of any additional communications you

02:04PM

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1 had with the FDA.

2 MR. ROGERS: And can we pull up Exhibit 5602.

3 And, Your Honor, this is, I believe, was one of the
4 documents that we agreed would be admitted in evidence but
5 there's a redaction issue so I'm not going to publish this.

02:05PM

6 BY MR. ROGERS:

7 Q. And Mr. Van Vleet, can you describe for the jury what this
8 is, please?

9 A. This is another FDA contact report, basically meeting
10 minutes or a description of a meeting with Bard personnel and
11 FDA personnel.

02:05PM

12 Q. Can you tell from this who requested the meeting?

13 A. I can't tell from this specific page, but I do know that I
14 requested the meeting.

15 Q. Well, let me, I guess, orient the jury a little bit more.
16 So what's the date of this document?

02:05PM

17 A. January 7th, 2010.

18 Q. And so would this have been before or after the Eclipse
19 Filter had been cleared?

20 A. This would be after. I would have to go back to the dates,
21 I'm sorry. I think it's --

02:05PM

22 Q. Okay.

23 A. Actually it's before. It was a short period of time
24 before, maybe 15 days before.

25 Q. Okay. And can you describe generally what the purpose of

02:06PM

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1 this meeting was?

2 A. Sure. So I will read from the subject here. It says:

3 Recovery G2, G2X fractures and Nicholson publication slash

4 presentation. So Bard had become aware of a meeting at which a

5 cardiologist had presented the results of a study that he

02:06PM

6 conducted at his institution that had a variety of

7 complications at rates that were very different than had been

8 previously observed in Bard's or anybody else's filters. And

9 we had experienced a challenge in collecting the detail behind

10 this. You have to make a reasonable effort to report

02:06PM

11 everything. And I believe there were 15 different attempts at

12 collecting the data on these reported or alleged complications

13 and we had not been successful.

14 So part of it, I think, was hoping the FDA might reach

15 out directly to the physician and ask him to please provide the

02:07PM

16 requested information.

17 Q. When you were describing the 15 separate attempts to try

18 and contact Dr. Nicholson, what types of things did Bard do to

19 try and get additional information from Dr. Nicholson?

20 A. Sure. Technically, attempt could be something as simply as

02:07PM

21 an e-mail or a telephone call. But I do know in this case that

22 at least six of the attempts were made directly in person at

23 the hospital.

24 Q. And so if you look up at the top of this document, did the

25 meeting take place in January of 2010?

02:07PM

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1 A. Yes. January 7th.

2 Q. And was this before the Nicholson study had actually been
3 published?

4 A. This was before the Nicholson study had been published.

5 Q. And how many folks from the FDA attended this meeting?

02:07PM

6 A. About 10, a dozen, maybe.

7 Q. And how many people from Bard attended the meeting?

8 A. 10.

9 Q. And from looking at the list of names of the FDA

10 participants, are several of those individuals medical doctors?

02:08PM

11 A. Yes.

12 Q. And at this particular meeting, was the focus exclusively
13 the Nicholson study?

14 A. That was the reason, the stated reason for meeting. But it
15 was just to discuss just in general the -- yeah. I think that
16 was the main reason for the meeting, but there was a lot of
17 data, additional data, that was presented to the FDA.

02:08PM

18 Q. Was a PowerPoint presentation given to FDA?

19 A. Yes.

20 MR. ROGERS: And can we pull up Exhibit 5942.

02:08PM

21 And, Your Honor, may we publish? This has been
22 admitted.

23 THE COURT: You may.

24 BY MR. ROGERS:

25 Q. Mr. Van Vleet, is this the entire PowerPoint presentation

02:09PM

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1 that was given to the FDA in January of 2010?

2 A. Yes.

3 Q. If we go over, I guess, to Page 6, please. And was this
4 some information that was presented to FDA?

5 A. Yes.

02:09PM

6 Q. So why did you discuss risks of pulmonary embolism with
7 FDA?

8 A. So while several, probably half of the reviewers were
9 medical doctors, many of the reviewers and the other personnel
10 present would be engineers. And it's really important that
11 everybody kind of understands the medical purpose for the use
12 of the device. So this is more of a background slide.

02:09PM

13 Q. Let's go over to Page 9. And Mr. Van Vleet, what type of
14 information is this, and why was it presented to FDA?

15 A. So with any decision FDA makes, they look at things in
16 terms of risk and benefit. And so this had some of the
17 benefits associated with it. Presumably there's another one
18 with the risks.

02:09PM

19 MR. ROGERS: Let's move over to Page 19, please. And
20 pull that out.

02:10PM

21 BY MR. ROGERS:

22 Q. And what is this?

23 A. This is our summary of what we had learned from the
24 presentation by a cardiologist at York Hospital.

25 Q. You say a presentation. Do you know what the context of

02:10PM

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1 the presentation was?

2 A. Sure. This is a meeting that's hosted, I believe, on a
3 monthly basis by a cardiologist in Washington, D.C. It's kind
4 of like a grand rounds meeting where people will come present
5 interesting information or different information to their
6 medical peers.

02:10PM

7 MR. ROGERS: Let's go to Page 21. And pull that out,
8 please.

9 BY MR. ROGERS:

10 Q. And Mr. Van Vleet, what is this information?

02:10PM

11 A. So this is kind of a walk-through to the FDA of the steps
12 that we took as soon as we became aware of this information
13 from Dr. Nicholson.

14 Q. And with that last bullet it says: 13 additional attempts
15 to gather details. Do you see that?

02:11PM

16 A. Yes.

17 Q. Why were you telling FDA that information?

18 A. Well, number one, to make sure that they understood that we
19 had followed through and tried to get the information that they
20 request us to submit on that. But also hopefully they would
21 maybe reach out on our behalf and try to help us obtain this
22 information.

02:11PM

23 Q. And can we go to Page 28 -- or excuse me -- 26 of the
24 document.

25 MR. ROGERS: Would you pull that out?

02:11PM

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1 BY MR. ROGERS:

2 Q. Mr. Van Vleet, was this information presented to FDA?

3 A. Yes.

4 Q. And describe for the jury, please, what this information
5 is.

02:11PM

6 A. This is a listing of all the fractures for the Bard filters
7 that were known to the company or reported by anybody to the
8 company.

9 Q. And how about let's move on to Page 28. And pull that out.
10 And Mr. Van Vleet, can you describe for us what this
11 information is?

02:12PM

12 A. So this is a summarization of the studies that have been
13 conducted by other IVC filter manufacturers in support of their
14 applications to FDA.

15 Q. And was this information reviewed with FDA as part of this
16 meeting?

02:12PM

17 A. Yes.

18 MR. ROGERS: Let's move on to Page 34. And pull that
19 out.

20 BY MR. ROGERS:

02:12PM

21 Q. And what is this information?

22 A. This was a summary of all of the migrations for Bard
23 filters from 2005 forward that were known to the company or
24 reported to the company.

25 MR. ROGERS: You can take that down, Scott. Thank

02:12PM

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1 you.

2 BY MR. ROGERS:

3 Q. Mr. Van Vleet, following this meeting, what was the result?

4 Did it lead to some sort of path or something of that nature?

5 A. I think the discussions continued, but I think our attempt 02:13PM

6 or our desire in having this meeting is, are we doing something

7 that -- or are we not doing something that you think we should

8 be doing? Is there another step that you think is appropriate

9 for Bard to take given the things that had been said? And we

10 felt that there was resolution at that meeting. 02:13PM

11 Q. Let me change gears on you, Mr. Van Vleet. Are you

12 familiar with something called FDA down-classification?

13 A. Yes.

14 Q. And can you tell the jury what that is, please?

15 A. So FDA has, at times, moved to change the classification of 02:13PM

16 a device. Essentially there are three types of device

17 classification: Type I, Type II, and Type III in the United

18 States classification system. Type I is something maybe as

19 simple as a cane or perhaps a Band-aid. Type II in this case

20 would be a filter, certain types of stents, balloon 02:14PM

21 angioplasty. Type III are generally implantable devices that

22 require a more comprehensive level of data to be provided. So

23 a down-classification by definition is when FDA lowers the

24 classification of a device.

25 Q. When you were working at C.R. Bard on IVC filters, did you 02:14PM

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1 come to learn that the FDA had down-classified IVC filters?

2 A. Yes.

3 Q. And can you tell us what the change in class was?

4 A. Sure. I believe this happened in 1996, and the panel of
5 physicians that review these types of applications requested
6 that this be down-classified from a Class III to Class II.

02:14PM

7 Q. And since that time, have you learned that there was an FDA
8 memo from 1996 regarding the down-classification of IVC
9 filters?

10 A. Yes.

02:15PM

11 Q. Can I pull up Exhibit 5877, please.

12 Mr. Van Vleet, you have on your screen Exhibit 5877.
13 Is that the memo that you were referring to?

14 A. Yes.

15 MR. ROGERS: Your Honor, at this time I would move
16 5877 into evidence.

02:15PM

17 MR. CLARK: Objection, Your Honor. Cumulative. Also
18 if you look on Pages 8 and 9 it appears to be a draft of some
19 sort. This is not a Bard document.

20 THE COURT: Let's address this for a minute at
21 sidebar, counsel.

02:15PM

22 Feel free to stand up.

23 (Discussion was had at sidebar out of the hearing of
24 the jury:)

25 THE COURT: What are you talking about?

02:15PM

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1 MR. CLARK: For one thing, Your Honor, this appears to
2 be a draft of some sort. There are handwritten edits,
3 highlights, things like that. We also don't have -- this is
4 not a Bard document. So again, not knowing that this is a
5 final publication.

02:16PM

6 THE COURT: Your objection besides cumulative is what?

7 MR. CLARK: It's not the authentic, final version of
8 what went out to the public. It's also hearsay, Your Honor. I
9 don't think it can be established as a business record.

10 THE COURT: As a what?

02:16PM

11 MR. CLARK: As a business record or regularly
12 conducted activity.

13 MR. ROGERS: Your Honor, this is a certification we
14 have gotten from the FDA via FOIA service which contains the
15 memorandum here that certifies that this document did come from
16 FDA.

02:16PM

17 THE COURT: Hold on just a second.

18 So my question is under Rule 902.1, is this a seal of
19 the United States? That's what you are asserting?

20 MR. ROGERS: 902.1.

02:17PM

21 THE COURT: I'm just trying to understand how you are
22 wanting to use this certificate at the beginning.

23 MR. ROGERS: Yes, Your Honor. I would say this is a
24 seal under 902.1 and that should address any issues about the
25 authentication document.

02:18PM

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1 THE COURT: Is there a signature?

2 MR. ROGERS: There is a signature here. I can't read
3 it upside down.

4 THE COURT: Let me look at it. So this is a custodian
5 of records certificate. So in other words, what this is is a
6 certificate confirming that this is a -- here's the affidavit.

02:18PM

7 So it looks to me as though the affidavit of Katherine Uhl,
8 which is certified with a certificate on the front and
9 notarized states that it is a certified authentic copy of the
10 records from the Food and Drug Administration.

02:19PM

11 So my question to you, Mr. Clark, is why is not that
12 affidavit and the certificate sufficient to authenticate this
13 as an FDA document?

14 MR. CLARK: I think that that affidavit and
15 certificate is sufficient for authentication. I don't think it
16 cures the hearsay problem.

02:19PM

17 THE COURT: Well, if it's authenticated.

18 MR. CLARK: We didn't have that seal, by the way.
19 Apologize.

20 THE COURT: If it's authenticated as a government
21 document, then why doesn't 803.8 then apply? It's a record of
22 a public office. It would seem to set out the office's
23 activities.

02:19PM

24 MR. CLARK: I think it's Part 2 from information
25 observed during their legal duty to report. This is an

02:19PM

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1 internal thing.

2 THE COURT: It can be any of those. Part A elements
3 are disjunctive. It could can be 1, 2, or 3.

4 MR. CLARK: I think we're down to cumulative. You
5 persuaded me. Again, I didn't have the seal.

02:20PM

6 THE COURT: That's fine. Why do you think it's
7 cumulative? What it cumulative of?

8 MR. CLARK: We have had number of witnesses talk about
9 down-classification. We heard that from Tillman. We heard
10 from his own testimony. So this document doesn't do anything
11 but pile on.

02:20PM

12 THE COURT: What's your response?

13 MR. ROGERS: Well, Your Honor, we attempted to put
14 this document in with Dr. Tillman when she testified. They
15 objected. So the jury has not seen this document so I don't
16 think that this is cumulative. It is some new information
17 about the down-classification process that the jury has not
18 seen. And so I think it's just additional information that is
19 new.

02:20PM

20 THE COURT: Just so we have a clear record, my
21 understanding, Mr. Clark, from our discussion, cumulative is
22 the only objection you are making to the document now?

02:20PM

23 MR. CLARK: In reviewing it, I think there's a
24 relevance issue, too, Judge, because we're talking about this
25 is undisputed this is a Class II device the whole time. The

02:21PM

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1 implication that they are trying to draw is these things have
2 been recognized by FDA that it's safer. I don't think that's
3 an important part of the inquiry that's in front of this jury.

4 THE COURT: Okay. I'm going to overrule the relevancy
5 and cumulative objections. So I will admit the document.

02:21PM

6 (In open court.)

7 THE COURT: Thank you Ladies and Gentlemen.

8 The objection is overruled, and Exhibit 5877 is
9 admitted.

10 BY MR. ROGERS:

02:21PM

11 Q. Mr. Van Vleet, do you have the document in front of you?

12 A. Yes.

13 Q. Have you had a chance to review this document?

14 A. Yes.

15 Q. If you would, let's turn to Page 4 of the document, please.

02:21PM

16 And is this a section of the document that relates to known
17 risks of IVC filters?

18 A. Yes.

19 Q. And if we move down to Section E, do you see Section E?

20 Mr. Van Vleet, if you would, what did this memo that FDA
21 prepared about the down-classification of IVC filters, what
22 information did it provide about the occurrence of filter
23 migration?

02:22PM

24 A. I will read directly from the document: The design of the
25 filter must be such that it is stable within the vena cava.

02:22PM

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1 The filter release mechanism that is part of the delivery
2 system must be simple and controlled such that the filter is
3 deployed in the desired location and it is completely opened.
4 If it is not it can ultimately propagate into the right heart
5 or it may tilt such that its filtering efficiency is
6 compromised.

02:22PM

7 Q. Let me interrupt you, Mr. Van Vleet.

8 MR. ROGERS: Your Honor, may we publish? I don't
9 believe the jury has it on the screen.

10 THE COURT: Yes, you may.

02:23PM

11 BY MR. ROGERS:

12 Q. I'm sorry, Mr. Van Vleet. Can you just pick up where you
13 were?

14 A. Sure. If it is not, it can ultimately propagate into the
15 right heart or it may tilt such that its filtering efficiency
16 is compromised. The occurrence of filter migration in the
17 literature varies from 6 percent to 53 percent. And there's
18 references cited.

02:23PM

19 Q. And this information, or the memo is written in 1996, is
20 that right?

02:23PM

21 A. Yes, sir.

22 Q. If you would, what is the next sentence about filter
23 migration?

24 A. Minor filter migration in the caudal or cephalic direction
25 is commonly reported and does not appear to be associated with

02:23PM

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1 clinically significant events.

2 Q. And was that information that the FDA was considering in
3 1996?

4 A. Yes, sir.

5 MR. ROGERS: And let's move on to Section F.

02:23PM

6 Would you pull that out, please?

7 BY MR. ROGERS:

8 Q. Mr. Van Vleet, what did the FDA say in regard to caval
9 penetration in this memo?

10 A. The filter must be designed such that it is secure within
11 the vena cava without penetrating the wall of this vessel and
12 potentially penetrating nearby organs. Slight penetration of
13 the caval wall by filter struts is usually asymptomatic and
14 clinically insignificant, perhaps because penetration occurs
15 gradually allowing time for the vessel wall to fibrose.

02:24PM

02:24PM

16 Q. And did it report a rate?

17 A. A caval penetration rate of 9 percent has been reported.

18 Q. And let's move on to Section J. Well, before we move on to
19 J, I'm sorry, underneath F there's G. And what does that
20 section address?

02:24PM

21 A. Filter tilting and angulation.

22 Q. And so what did the FDA include in this memo regarding
23 filter tilting?

24 A. The significance of tilting and angulation of caval filter
25 after placement is controversial. There is a theoretical loss

02:25PM

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1 of filtering efficacy of any filter when tilted or angulated
2 significantly. However, there is no good clinical data to
3 support a definite increased incidence in PE or failure to trap
4 thrombi. A properly designed device should minimize the
5 possibility for tilting upon deployment or angulating after
6 implantation. This risk can be controlled by special controls.

02:25PM

7 Q. Thank you.

8 MR. ROGERS: You can pull that down. Can we move to
9 the next, Page 7? And under the Section J, can you pull that
10 out, please?

02:25PM

11 BY MR. ROGERS:

12 Q. And what did this section regarding fracture of filter have
13 in it regarding these filters at that time?

14 A. Filters may fracture as a result of direct trauma to the
15 abdomen or from a metal fatigue phenomenon when perforation
16 exists and the tip of the leg becomes locked into a vertebral
17 body or adjacent and mobile tissues whereby the respiratory
18 motion may then cause repeated unanticipated flexion of the
19 filter leg, or it may fracture due to metal corrosion and weld.
20 The fracture fragments may migrate locally or distally. This
21 complication --

02:26PM

22 Q. Continue. I'm sorry.

23 A. This complication usually is asymptomatic and requires no
24 treatment. The incidence of occurrence has been reported at 2
25 percent. Filter fracture is a function of design and delivery

02:26PM

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1 into the IVC. The risk can be controlled by special controls.

2 Q. Was all of this information information that FDA considered
3 in 1996 in making a determination whether IVC filters should be
4 down-classified?

5 A. Yes.

02:26PM

6 Q. And I believe you told us earlier that the FDA ultimately
7 did decide to down-classify IVC filters from Class III to Class
8 II.

9 A. Yes.

10 MR. ROGERS: You can take that down, please.

02:27PM

11 BY MR. ROGERS:

12 Q. Mr. Van Vleet, let's kind of move forward chronologically.
13 We were just looking at a document from 1996, and I want to
14 bring us back to the year 2010.

15 And were you familiar with an FDA safety communication
16 that was issued by FDA in 2010 regarding IVC filters?

02:27PM

17 A. Yes.

18 MR. ROGERS: And can we pull up Exhibit 6911?

19 Excuse me. I misspoke. It's 6991.

20 Your Honor, may we publish? This as in evidence.

02:27PM

21 THE COURT: Yes, you may.

22 BY MR. ROGERS:

23 Q. Mr. Van Vleet, is this the safety communication?

24 A. Yes.

25 Q. And were you the regulatory affairs vice president when

02:27PM

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1 this safety communication was issued?

2 A. Yes, I was.

3 Q. And did Bard undertake some effort in order to send
4 information out regarding this safety communication?

5 A. Yes.

02:28PM

6 MR. ROGERS: And if we could, could we pull up Exhibit
7 5923.

8 And, Your Honor, this -- I'm not going to publish this
9 again because -- well, I take it back. Your Honor, I believe
10 this has been moved into evidence, although I'm not sure if
11 there was any issues about it.

02:28PM

12 THE COURT: Is this 5923?

13 MR. ROGERS: It is 5923.

14 MR. CLARK: No objection.

15 THE COURT: We show it in evidence.

02:28PM

16 BY MR. ROGERS:

17 Q. So Mr. Van Vleet, can you tell us please what this letter
18 is?

19 A. It's a letter to -- it's addressed to: Clinical Caregiver.

20 Q. And are you the person that signed the letter?

02:28PM

21 A. Yes.

22 Q. And so what was the purpose of this?

23 A. It was to respond to what I felt were numerous questions
24 that we had received or I had received personally from
25 physicians and other customers and reflecting maybe some

02:29PM

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1 concerns or confusion about the initial communication, the
2 safety communication.

3 Q. And in the third paragraph there, that first sentence, can
4 you read that for the jury, please?

5 A. All vena cava filters have the potential for complications. 02:29PM

6 Dr. Bram Zuckerman, the director of FDA Center for Devices and
7 Radiological Health Division of Cardiovascular Devices was
8 quoted recently in an interview with the Associated Press
9 wherein he indicated that problems had been seen with all
10 retrievable filters and that FDA is in the process of 02:29PM
11 completing an analysis of data on filter problems generally.

12 MR. ROGERS: Your Honor, may we publish?

13 THE COURT: After the break. We're going to break
14 until 2:45, Ladies and Gentlemen.

15 (Recess from 2:29 p.m. until 2:46 p.m.) 02:29PM

16 THE COURT: You may continue, Mr. Rogers.

17 MR. ROGERS: Thank you, Your Honor.

18 THE COURT: Go ahead.

19 MR. ROGERS: Your Honor, before the break I had asked
20 if we could publish Exhibit 5923 which has been admitted. 02:46PM

21 THE COURT: Yes, you may.

22 BY MR. ROGERS:

23 Q. And Mr. Van Vleet, on your screen, is this the letter that
24 you had authored and sent out in September of 2010?

25 A. Yes. 02:46PM

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1 Q. And up at the top, it says: Dear Clinical Caregiver. Do
2 you see that?

3 A. Yes.

4 Q. And how did you decide who would receive a copy of this
5 letter?

02:46PM

6 A. So it would have been a combination of anybody that's
7 involved in the receipt of IVC filters, whether it was a
8 purchasing person, a hospital employee, or physicians that we
9 knew had used the device.

10 Q. And there in the second paragraph, that last sentence.

02:46PM

11 MR. ROGERS: Would you pull that out, please, Scott?

12 Thank you.

13 BY MR. ROGERS:

14 Q. And what in this sentence did you encourage doctors to do?

15 A. So we encouraged physicians to review the FDA initial
16 communication and to consider the risks and benefits of filter
17 removal for each patient.

02:47PM

18 MR. ROGERS: You can take that down. Thank you.

19 And can we pull up Exhibit 7960.

20 BY MR. ROGERS:

02:47PM

21 Q. And Mr. Van Vleet, can you see the exhibit?

22 A. Yes.

23 Q. And can you tell the jury just generally what this is
24 without going into a description of it?

25 A. Sure. It's a summary of all of the clinical studies that

02:47PM

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1 have been conducted, I believe, in support of FDA application
2 for clearance.

3 Q. And were you personally involved in the creation of this
4 handout?

5 A. Yes.

02:47PM

6 Q. What was your involvement?

7 A. As regulatory head, it's my responsibility to approve and
8 make sure that all of the information is accurate and it's also
9 appropriately contexted and that it's fair and balanced.

10 Q. And from time to time, did Bard prepare handouts to provide
11 to physicians and other health care providers?

02:48PM

12 A. Yes.

13 MR. ROGERS: Your Honor, at this time I move this
14 document into evidence.

15 MR. CLARK: No objection.

02:48PM

16 THE COURT: Admitted.

17 MR. ROGERS: May we publish?

18 THE COURT: You may.

19 BY MR. ROGERS:

20 Q. Mr. Van Vleet, now that the jury has seen the document, can
21 you describe just physically how this would be used? Well,
22 strike that question.

02:48PM

23 I'm really trying to -- was this something that would
24 be laminated?

25 A. It would have been something that could be left with a

02:48PM

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1 customer.

2 Q. And would it be something that would be left behind for the
3 customer at their office?

4 A. Yes. That would have been the intention.

5 Q. And can you tell the jury what your thought process was in
6 assembling this information?

02:48PM

7 A. The purpose for pulling this together was to context the
8 clinical performance of the Bard filters with the clinical
9 performance of other filters on the market.

10 Q. And the first column that we see there is the EVEREST
11 study. Do you see that?

02:49PM

12 A. Yes.

13 Q. And that study is the study you previously discussed that
14 relates to the G2?

15 A. Yes.

02:49PM

16 Q. How about these other studies that we may not recognize?
17 We see Olivia, Charles, Lynch, Cantwell, Lynch. Do you see
18 those?

19 A. Yes.

20 Q. What are those studies?

02:49PM

21 A. So if you look at the second list down where it says
22 "filter," that identifies the actual product that the studies
23 were evaluating. So the first one, two, three, four five, six
24 studies are Bard products and then the last four would be other
25 competitive products, probably the more recent products cleared

02:49PM

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1 on the market.

2 Q. It looks like you also included a column for the Nicholson
3 study, is that right?

4 A. Yes.

5 Q. What was your thinking in including information about that
6 study?

02:49PM

7 A. The data that was summarized by Dr. Nicholson was so
8 completely different than anything we had seen in the
9 literature about either Bard filters or any other filter, and
10 we had some specific concerns about the data.

02:50PM

11 Q. And the last four columns, you have got four separate
12 studies there. And do those studies involve Bard filters?

13 A. No.

14 Q. And what was the purpose of including the information about
15 those studies?

02:50PM

16 A. I think those were -- well, for sure, option -- those were
17 other major filters being used by the interventional radiology
18 community.

19 Q. And are all the studies that are contained in this handout
20 studies that a doctor could go look up in the published
21 literature?

02:50PM

22 A. Yes.

23 Q. Can we go to the second page of the handout?

24 And on this particular page there is some complication
25 rates down there. Do you see that?

02:51PM

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1 A. Yes.

2 Q. And there's a column there for G2. Do you see that?

3 A. Yes.

4 Q. And where does that information come from?

5 A. That comes from, I believe that comes from the IFU, the
6 Instructions For Use and the data initially -- or originated in
7 the EVEREST clinical trial.

02:51PM

8 Q. And I'm sorry, did you say the EVEREST clinical trial?

9 A. Yes.

10 Q. Okay. And as far as the rates of fracture are concerned,
11 what are the rates that are reported there for Bard and the
12 other filters?

02:51PM

13 A. Bard had a rate of 1.2 percent. That was the one patient
14 with the, I think, 82 patient denominator. Celest had no
15 reported fractures. And the Tulip study, Gunther Tulip study
16 they were not recorded or reported in the study, so we
17 attempted to context it the way it was known to us. And then
18 Option and OptEase had no fractures.

02:51PM

19 Q. Do each of these columns represent information from one
20 clinical study?

02:52PM

21 A. Yes.

22 Q. Mr. Van Vleet, just to wrap up, you were at Bard for a
23 little bit more than 11 years, is that right?

24 A. 10 and-a-half years.

25 Q. 10 and a half. Excuse me. Were you familiar with the

02:52PM

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1 internal processes at Bard regarding corrective actions?

2 A. Yes.

3 Q. And throughout the course of your time at Bard, did it ever
4 become to a point where Bard felt like there was any corrective
5 action that needed to be done regarding its IVC filters based
6 on the internal data that the company had?

02:52PM

7 A. No.

8 Q. And has Bard ever made a decision that any of its -- the
9 IVC filters on the market while you were there, starting with
10 the G2, that any of those filters should be recalled?

02:53PM

11 A. No.

12 Q. Thank you, Mr. Van Vleet. I have no further questions.

13 THE COURT: Cross-examination.

14 MR. CLARK: Yes, Your Honor.

15 Your Honor, may I be permitted to approach the witness
16 and provide him a copy of his transcript from testimony a few
17 months ago?

02:53PM

18 THE COURT: Sure. Why don't you just give it to
19 Traci. She'll hand it to him.

20 CROSS-EXAMINATION

02:53PM

21 BY MR. CLARK:

22 Q. Afternoon, Mr. Van Vleet. I'm going to go through a couple
23 things in a sort of scattered fashion just to pick up on a few
24 points Mr. Rogers raised with you.

25 With respect to the letter that you designed to go to

02:53PM

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1 customers and people who used IVC filters, do you remember that
2 testimony?

3 A. Yes.

4 Q. It was Exhibit 5923? Take my word for it?

5 A. I will take your word for it.

02:54PM

6 Q. Now, that letter did not contain any warning rates or
7 anything about fractures, tilt, migration, with respect to
8 Bard's G2 family of filters. Is that correct?

9 A. Yeah. The text of that letter did not contain any specific
10 rates.

02:54PM

11 Q. Okay. And in terms of the document you were shown from
12 1996 that was the down-classification memo?

13 A. Yes.

14 Q. The solution that the authors concluded there was that
15 fracture is something that would be a function of the filter's
16 design and implantation. Do you remember that?

02:54PM

17 A. I know that those words were there. I'd have to see the
18 actual text to see.

19 Q. Well, you read those words to the jury today. Right?

20 A. Uh-huh.

02:54PM

21 Q. That's a yes?

22 A. Yes, I read those words.

23 Q. You were asked some questions about Dr. Nicholson's study.
24 Just to be clear, Dr. Nicholson has never been a consultant or
25 a thought leader or anybody compensated by Bard. Is that

02:55PM

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1 right?

2 A. Not to my knowledge.

3 Q. And the FDA was concerned after receiving information about
4 that study, and that's what prompted the meeting where you
5 assembled a team of 9 or 10 people to meet with the FDA, right?

02:55PM

6 A. Bard was concerned, and we -- actually I personally called
7 the meeting.

8 Q. You illustrated some statistics at the bottom of Exhibit
9 7960. Do you remember that, where we talked about filter
10 migration rates, fracture rates, tilt rates, things like that?
11 You just gave that testimony to Mr. Rogers. Do you remember
12 that?

02:55PM

13 A. I would have to look at and see. Was that the clinical
14 study report or --

15 Q. Let me see if I can put this up. Will that show on his
16 screen?

02:55PM

17 THE COURT: You want it shown to the witness?

18 MR. CLARK: Yes, please.

19 THE COURT: What is this?

20 MR. CLARK: This is Exhibit 7690.

02:56PM

21 THE COURT: Do you want it displayed to the jury?

22 MR. CLARK: Sure.

23 THE COURT: Okay.

24 MR. CLARK: Thank you.

25 BY MR. ROGERS:

02:56PM

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1 Q. Now, this what we're looking at here with my finger, those
2 are the rates that came from the EVEREST trial, right?

3 A. Correct.

4 Q. And the fracture rate was higher than any of the other
5 filters recorded, correct?

02:56PM

6 A. It is numerically higher than any of the other filters.

7 Q. And the caudal migration rate was higher than any of the
8 other filters, right?

9 A. Yes. It also was numerically higher than others.

10 Q. And the filter tilt of greater than 15 degrees was
11 numerically higher than any of the other filters, correct?

02:56PM

12 A. It would be hard to say, because I don't believe the filter
13 tilt was reported in those studies.

14 Q. The penetration rate was higher than the other recorded
15 filters, correct?

02:56PM

16 A. In three of them, correct.

17 Q. And one of the ones just didn't have the information?

18 A. Didn't have that information included.

19 Q. And that's all information that was also in the Binkert
20 article that you talked about with Mr. Rogers, correct?

02:56PM

21 A. The EVEREST information was. I'm not sure if the other
22 competitive filters were.

23 Q. What I'd like to do in the interest of time, is to ask you
24 a series of questions. And I think they are all capable of you
25 can tell me if it's true or false, and if it's not true or

02:57PM

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1 false I have got a little category here where you can tell me I
2 can't answer true or false. Is that fair?

3 A. Sure. Yes.

4 Q. And could I show the witness these questions one at a time?

5 THE COURT: Show the questions to the witness?

02:57PM

6 MR. CLARK: Yes.

7 THE COURT: Yes. You can show the questions to the
8 witness.

9 MR. CLARK: Sure.

10 BY MR. CLARK:

02:57PM

11 Q. Can you see that, sir?

12 A. Yes.

13 Q. Got a little controlled question here. First one is: Your
14 name is John Van Vleet. Is that true or false or I can't
15 answer true or false?

02:57PM

16 A. That is true.

17 Q. Now, second statement: The FDA relies on medical device
18 manufacturers to provide truthful, accurate, and reliable
19 information about medical devices. True, false or I can't
20 answer true or false?

02:58PM

21 A. That is true.

22 Q. Dr. Scott Trerotola was a paid consultant for Bard during
23 your tenure with Bard?

24 A. That is true.

25 Q. During your tenure with Bard, Dr. Jay Nicholson published a

02:58PM

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1 study raising concerns about the number of recovery and G2

2 Filter fractures doctors at his hospital found in a study.

3 A. True.

4 Q. Bard lost filter sales as a result of Dr. Nicholson's

5 study.

02:58PM

6 A. I can't answer true or false.

7 Q. Fair enough.

8 One of Bard's responses to the Nicholson study was to

9 try to launch the Eclipse Filter ASAP. Do you remember that?

10 A. I don't believe that's true. I believe that's false.

02:58PM

11 Q. That's false.

12 The only design difference between the Eclipse Filter

13 and the G2 is that the Eclipse is electropolished?

14 A. The base wire for the Eclipse is electropolished, correct.

15 Electropolishing is the change. True.

02:59PM

16 Q. Put that in the true category?

17 A. Yes.

18 Q. The Eclipse Filter does not contain caudal anchors?

19 A. True.

20 Q. Caudal anchors reduce caudal migration?

02:59PM

21 A. Caudal anchors are designed to reduce caudal migration.

22 Q. True?

23 A. I believe that's true.

24 Q. And these are just based on your belief. I understand if

25 you have a question you can tell me you can't answer true or

02:59PM

~~5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Van Vleet-Cross~~

1 false.

2 Bard understood as early as 2006 caudal anchors can
3 reduce caudal migration.

4 A. I can't answer true or false.

5 Q. Bard understood from the EVEREST trial that we have heard
6 about that migration can lead to tilt, perforation, and
7 fracture.

02:59PM

8 A. I probably have to say I can't answer true or false on
9 that.

10 Q. Fair enough. At the time Bard was seeking FDA clearance
11 for the Eclipse Filter, it had plans to create a filter with
12 caudal anchors.

03:00PM

13 A. I'm a little rusty on my chronology, so I don't know
14 exactly when the filter with caudal anchors was begun to be
15 designed. But it sounds reasonable. But I would have to look
16 at the dates because the projects start at different times.

03:00PM

17 Q. We'll put that as can't answer true or false to be fair.

18 A. That's fine.

19 Q. The filter with caudal anchors became the Meridian?

20 A. Correct.

03:00PM

21 Q. Now, caudal anchors made the Meridian 16 times for
22 resistant to caudal migration than the Eclipse?

23 A. I can't answer. It sounds like a good number but I would
24 have to look at the report.

25 Q. Do you have independent recollection that the addition of

03:00PM

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1 caudal anchors did make that filter more resistant to caudal
2 migration?

3 A. It stands to reason. I just don't know what the numbers
4 were for sure.

5 Q. The FDA did not do any independent testing of the G2 or
6 Eclipse filters, right?

03:01PM

7 A. So I do know that we tested the Eclipse Filter because we
8 didn't have the capability to do some of the testing. So there
9 was other external labs involved in the testing.

10 Q. FDA labs?

03:01PM

11 A. I'm sorry?

12 Q. FDA labs?

13 A. FDA did have a lab, and we agreed on the way the testing
14 should be conducted, but it was an independent test house, like
15 Manasi or somebody.

03:01PM

16 Q. To your knowledge, the FDA itself never independently
17 tested either of these filters?

18 A. I don't know if they did or not. I know they have an
19 Office of Science and Laboratories.

20 Q. We'll put you down for can't answer true or false. Fair?

03:02PM

21 A. Okay.

22 Q. Controlled question: Your name is still John Van Vleet?

23 A. Yes, that's true.

24 Q. Dr. John Lehmann was an independent consultant for Bard
25 during some of your tenure at Bard, correct?

03:02PM

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1 A. I believe so. I have never met him.

2 Q. Dr. Lehmann was originally going to be the person who
3 signed Bard's submission to the FDA reporting on the EVEREST
4 trial. True?

5 A. I don't know. I wasn't there. I didn't -- I didn't hire
6 him so I -- it sounds reasonable, but I don't know what his
7 role was or who was giving him direction.

03:02PM

8 Q. Can't answer true or false for that one?

9 A. Yeah. I think that's probably good.

10 Q. Do you remember that Dr. Lehmann did not want to include
11 SIR guideline information in Bard's EVEREST trial submission?

03:02PM

12 A. I do remember e-mail discussions of that.

13 Q. That would be true?

14 A. Yes.

15 Q. Now, Dr. Lehmann didn't want to include the SIR guideline
16 information because they are not intended for anyone other than
17 physicians, right?

03:02PM

18 A. I believe that that may have been one of the reasons. I
19 really didn't understand his rationale.

20 Q. I will put that as a true with asterisk by it. Fair
21 enough?

03:03PM

22 A. Sure.

23 Q. Dr. Lehmann did not believe it would be truthful and
24 accurate for Bard to represent that the EVEREST trial
25 demonstrated that the G2 was substantially equivalent to

03:03PM

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1 similar devices.

2 A. I can't answer true or false. I'm not sure what was in his
3 head.

4 Q. In his proposed draft of the EVEREST trial submission, Dr.
5 Lehmann deleted the representation that the EVEREST trial
6 demonstrated substantial equivalence to similar devices?

03:03PM

7 A. I can't answer true or false to that.

8 Q. After getting this report back from Dr. Lehmann, you
9 requested that he be removed as the submitting author for the
10 EVEREST trial report?

03:04PM

11 A. I believe he was removed or I don't know. I actually saw
12 his name as one of the authors. But I can't remember true or
13 false.

14 Q. Well do you remember the part of that submission that Mr.
15 Rogers blew up for you and it was signed by Dr. Ciavarella and
16 not Dr. Lehmann?

03:04PM

17 A. I didn't look at that part, but yeah, if that's the way it
18 was.

19 Q. More to the point, did you ask that he be removed from this
20 project, Dr. Lehmann?

03:04PM

21 A. I can't recall if I specifically asked that he be removed
22 from the project. I know we had differences of opinions for
23 sure.

24 Q. I will skip the next one. I think you have already
25 answered it.

03:04PM

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1 The final report that was ultimately sent to the FDA
2 includes comparison data from the SIR guidelines. Is that
3 right?

4 A. I believe that's true.

5 Q. And we saw some of that today?

03:04PM

6 A. Uh-huh.

7 Q. Yes?

8 A. Yes. Uh-huh.

9 Q. The final report sent to the FDA indicates, quote, "The
10 overall study results constitute valid scientific evidence
11 regarding the overall performance of Bard Recovery G2 Filter
12 system as an IVC filter and serves as a valid basis for
13 comparison in determining that the Recovery G2 Filter is
14 substantial equivalent to similarly marketed devices.

03:05PM

15 A. That seems reasonable. I would have to look at the report
16 make sure.

03:05PM

17 Q. True with an asterisk?

18 A. Sure.

19 Q. To your knowledge, Bard never told, at least during your
20 tenure there, the FDA about Dr. Lehmann's concerns about
21 including the SIR guidelines in its EVEREST submission?

03:05PM

22 A. To my knowledge, no. True.

23 Q. To your knowledge, Bard never told the FDA about Dr.
24 Lehmann's concerns about the truthfulness of a statement that
25 the EVEREST trial data showed that the G2 Filter was

03:05PM

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1 substantially equivalent to other devices?

2 A. I can't answer true or false.

3 Q. To your knowledge that never happened, though, correct?

4 A. Yeah. To my knowledge, correct.

5 Q. As late as October 28, 2015 Bard employee Josh Smale was
6 representing to the medical community that the Simon Nitinol
7 Filter had a, quote, "safe track record of use for over 20
8 years," close quote?

03:06PM

9 A. It sounds reasonable.

10 Q. True with an asterisk?

03:06PM

11 A. I guess the part I don't understand is representing to the
12 medical community.

13 Q. Are you aware of him making that representation to others
14 involved in filter use?

15 A. I can't -- I guess I can't answer true or false on that
16 one.

03:06PM

17 Q. Would it surprise you if he did make that representation?

18 A. It wouldn't be surprising, no.

19 Q. If I could direct your attention, sir, to the transcript in
20 front of you from testimony you provided about two months ago,
21 I have tagged a few --

03:06PM

22 MR. ROGERS: Objection, Your Honor. I don't believe
23 there's been any question that's been asked that would make
24 impeachment proper.

25 MR. CLARK: I'm getting to that. I'm just trying to

03:07PM

~~5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Van Vleet-Cross~~

1 get him oriented.

2 THE COURT: I'm going to overrule at this point. Go
3 ahead.

4 BY MR. CLARK:

5 Q. Sir, I asked you some questions earlier about your
6 recollection of -- hang on one second here. Let me go to a
7 better document.

03:07PM

8 MR. CLARK: Gay, could you please pull up Exhibit
9 1036?

10 While she's pulling it up let me go back to that
11 transcript real quick.

03:07PM

12 BY MR. CLARK:

13 Q. I think you told me earlier, sir, that you did not recall
14 whether Mr. Dr. Lehmann had a concern about including a
15 statement that the EVEREST trial demonstrated substantial
16 equivalence between the G2 and similar devices. Do you
17 remember that testimony?

03:08PM

18 A. I'm sorry. Can you repeat the question? I was reading.

19 Q. Sure. Do you remember giving testimony earlier to me that
20 you did not recall Dr. Lehmann having a concern about including
21 a statement in the FDA submission on the EVEREST trial that the
22 G2 -- that the study demonstrated that the G2 was substantially
23 equivalent to other devices?

03:08PM

24 A. Can you say the very beginning part again?

25 Q. Yeah. Earlier when we were talking, you told me you

03:08PM

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1 couldn't say true false or --

2 A. Right.

3 Q. -- regarding that statement. Do you remember that?

4 A. Correct.

5 Q. So you don't have any recollection of Dr. Lehmann
6 expressing concern about including a statement to the FDA that
7 the EVEREST trial showed that the G2 was substantially
8 equivalent to other similar devices?

03:08PM

9 A. I don't have a specific recollection.

10 Q. Can I direct your attention to page 4547.63, which is, I
11 think, the third tab in the transcript I have laid before you?

03:09PM

12 A. .63?

13 Q. 063?

14 A. Yes.

15 Q. The question on Line 5 says, "On re-reading the document, I
16 realize that we have an unsupported regulatory statement that
17 needs modification relating to the EVEREST trial demonstrating
18 substantial equivalence to similar devices which it obviously
19 didn't do. So I have deleted that sentence."

03:09PM

20 And the question is, do you see that? You said you
21 did see that?

03:09PM

22 A. Uh-huh.

23 Q. Does that refresh your recollection that Dr. Lehmann had
24 some concerns about including that language?

25 A. It does. I would have to see what I was reading at the

03:09PM

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1 time to respond to that, but yes.

2 MR. CLARK: Let's go back to 1036, please, Gay.

3 BY MR. CLARK:

4 Q. Mr. Van Vleet, this is an e-mail that you authored,
5 correct?

03:10PM

6 A. Correct.

7 MR. CLARK: And if you could pull to the last
8 paragraph before the signature.

9 BY MR. CLARK:

10 Q. This e-mail is discussing some frustration that you were
11 encountering with Dr. Lehmann's proposed revisions to the
12 EVEREST trial submission to the FDA, correct?

03:10PM

13 A. Correct.

14 Q. And you had asked that Dr. Lehmann be reassigned from
15 authorship of this report, correct?

03:10PM

16 A. Correct. When this report was developed there was not a
17 director of clinical research or affairs at Bard Peripheral
18 Vascular. So now that there was, I felt it was appropriate
19 that we reassign the signature to John Reviere.

20 Q. You didn't like what Dr. Lehmann was proposing with his
21 revisions, correct?

03:10PM

22 A. I didn't understand what he was proposing, to be quite
23 honest with you, and he was 2500 miles away.

24 Q. And Dr. Lehmann was, in fact, reassigned from authorship of
25 that study, correct?

03:11PM

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1 A. It wouldn't surprise me that he was. But we certainly did
2 have John Reviere's signature on that.

3 Q. Lastly, you were asked some questions about the patient
4 brochure for the Eclipse?

5 A. Yes.

03:11PM

6 Q. And I didn't see anything in there about any relative
7 increase of risk of those complications associated with the
8 Eclipse Filter.

9 Is that fair? Those are not in there.

10 A. Increase in risk relative to what?

03:11PM

11 Q. Use of the Eclipse Filter.

12 A. Okay.

13 Q. Let me give you some context.

14 There's a number of complications that are listed in
15 that brochure, correct.

03:11PM

16 A. Correct.

17 Q. And but it doesn't say anything about whether this filter
18 makes those complications more or less likely than other
19 filters. Fair?

20 A. I don't believe that there was anything that made a
21 comparison one way or the other.

03:11PM

22 Q. Thank you, sir. No further questions.

23 THE COURT: Redirect?

24 MR. ROGERS: Very briefly, Your Honor.

25 Can we pull Exhibit 7960 back up? That is not what I

03:12PM

5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Van Vleet-Redirect

1 was looking for. The last exhibit we used.

2 THE COURT: 1036. Oh, that you used?

3 MR. ROGERS: I'm sorry. The last exhibit I used, the
4 handout. I may have written down the wrong number. Yes.

5 Thank you. Can we go to the second page, please?

03:12PM

6 REDIRECT EXAMINATION

7 BY MR. ROGERS:

8 Q. And Mr. Van Vleet, you were just asked some questions about
9 this bottom left portion there?

10 MR. ROGERS: Scott, would you mind blowing that up?

03:12PM

11 BY MR. ROGERS:

12 Q. You were asked some questions by plaintiff's counsel about
13 this. Do you recall that?

14 A. Yes.

15 Q. And was this chart, was that contained in this handout that
16 was to be provided to doctors about the Bard's IVC filters?

03:12PM

17 A. Yes.

18 Q. And Mr. Van Vleet, do you believe that this information was
19 fair and balanced about what these particular studies showed?

20 A. I do believe it was.

03:13PM

21 Q. And Mr. Van Vleet, has it been a while since you have taken
22 a true/false test?

23 A. Probably.

24 Q. And I expect you have never taken a true/false test in
25 court before, have you?

03:13PM

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1 A. I certainly have not.

2 MR. ROGERS: And if you would, can we go to the last
3 exhibit that was used, which was 1036?

4 BY MR. ROGERS:

5 Q. Mr. Van Vleet, were you asked some questions about this
6 particular e-mail?

03:13PM

7 A. Yes.

8 Q. And what's the date of that e-mail?

9 A. September 27th, 2007.

10 Q. So it's been more than 10 years ago since you wrote this
11 e-mail?

03:13PM

12 A. Yes.

13 Q. And Mr. Van Vleet, is it true or false that you can't
14 recall everything that you wrote in an e-mail 10 years ago?

15 A. That's very true.

03:13PM

16 Q. Thank you. No further questions.

17 THE COURT: All right, sir. You can step down.

18 MR. NORTH: Your Honor, at this time we would recall
19 Mr. Rob Carr to the stand.

20 THE COURT: If you want to stand up, Ladies and
21 Gentlemen, while he's coming in, feel free.

03:14PM

22 Mr. Carr, you are still under oath for purposes of the
23 trial, so you can come back to the witness chair.

24 ***

25 ***

5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct

1 ROB CARR,
2 called as a witness herein, having been previously sworn, was
3 examined and testified as follows:

4 DIRECT EXAMINATION

5 BY MR. NORTH:

6 Q. Good afternoon Mr. Carr.

7 A. Good afternoon.

8 Q. I believe the jury has met you a couple weeks ago, but now
9 I'd like to ask you a few questions myself.

10 Could you briefly describe for the jury your
11 educational background?

03:15PM

12 A. I have a Bachelor of Science in Biomedical Engineering from
13 the Catholic University of America in Washington, D.C.

14 Q. And what is biomedical engineering?

15 A. It's a discipline that marries the biological classes with,
16 in my case, mechanical engineering classes. Sometimes it's
17 electrical engineering. In my case it was mechanical.

03:15PM

18 Q. Do you live here in Phoenix?

19 A. I do.

20 Q. And are you married?

03:15PM

21 A. I am.

22 Q. And are you part of a medical sort of family?

23 A. Yes.

24 Q. Why did you become an engineer?

25 A. I was always interested in either becoming a veterinarian

03:15PM

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1 or a physician, and engineering seemed like a nice entree into
2 either of those at the time.

3 Q. Has most of your professional career since college been
4 involved with medical devices?

5 A. All of it.

03:16PM

6 Q. What was your first job after graduating from college at
7 Catholic University?

8 A. In Boston, I worked for a startup biotech firm called
9 Organogenesis.

10 Q. And can you tell us what Organogenesis does, or did?

03:16PM

11 A. Still does. We worked on collagen-based material, so it's
12 a natural protein in your body and we tried to create different
13 structural things out of it, blood vessels, urinary patches,
14 things like that.

15 Q. And for how many years did you work at Organogenesis?

03:16PM

16 A. About seven.

17 Q. And what was your position generally at that company?

18 A. I held different engineering positions. When I left I was
19 the director of R&D, research and development.

20 Q. And was NMT or Nitinol Medical Technologies your next job
21 after you left that company?

03:17PM

22 A. Yes, it was.

23 Q. And when did you join NMT?

24 A. September of 1996.

25 Q. What positions did you hold at NMT during your years there?

03:17PM

—5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct—

1 A. Again, different levels of R&D positions.

2 Q. What was your position at the time you left?

3 A. I think program director of R&D.

4 Q. And you left NMT to come to Bard?

5 A. I did.

03:17PM

6 Q. And what year was that?

7 A. July 1st, 2002.

8 Q. So you were with NMT approximately six years?

9 A. Yes.

10 Q. What product did you -- or products did you spend most of
11 your time working with while at NMT?

03:17PM

12 A. Vena cava filters as well as a device used to seal a hole
13 in your heart called a PFO.

14 Q. When you started working with IVC filters in the 1990s,
15 what type of filters were available?

03:18PM

16 A. Just permanent filters.

17 Q. What material are Bard's or NMT's filters made of?

18 A. Nitinol.

19 Q. Describe for us briefly what Nitinol is. How was it
20 originated?

03:18PM

21 A. So it's a material that was developed by the Navy, and it
22 is a shape memory, it's called, material that at one
23 temperature can be in one shape and then at a different
24 temperature can form into a different shape.

25 Q. While working at NMT, did you work with a physician by the

03:18PM

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1 name of Dr. Morris Simon?

2 A. Yes.

3 Q. Who was Dr. Simon?

4 A. He was a world renowned interventional radiologist at Beth
5 Israel Hospital in Boston. And he had developed what is the
6 Simon Nitinol Filter and was one of the founders of NMT
7 Medical.

03:19PM

8 Q. Was he considered a pioneer in the development of IVC
9 filters?

10 A. Absolutely.

03:19PM

11 Q. Did you work with Dr. Simon in the development of a new
12 filter after the introduction of the Simon Nitinol?

13 A. Yes. It became the Recovery Filter.

14 Q. Why were you and Dr. Simon working on the development of a
15 retrievable filter when you already had the Simon Nitinol
16 Filter on the market?

03:19PM

17 A. Dr. Simon and others that we worked with felt that there
18 were many patients who were getting permanent filters that
19 didn't necessarily need a permanent filter forever, that the
20 reason why they were getting a filter was temporary. And so
21 while unknown what that length would be, it was temporary.

03:19PM

22 And so he wanted to work to develop a filter, if we
23 could, that could be implanted, remain in forever, or be
24 removed at any time when it was no longer needed.

25 Q. From your work with Dr. Simon, did it appear that he was

03:20PM

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1 passionate about this project?

2 A. We were all very passionate about it.

3 Q. Besides Dr. Simon, were there other medical professionals
4 who assisted in the development of IVC filters at NMT?

5 A. Yes. There were several. The main ones was John Kaufman
6 who was an interventional radiologist at Mass General at the
7 time and Tony Venbrux, who was an in interventional radiologist
8 at Johns Hopkins in Baltimore at the time.

03:20PM

9 Q. Did you begin working on the development of what became the
10 Recovery Filter when you first started in 1996?

03:20PM

11 A. It was shortly after I started on the septal occluder
12 device first, but yes, certainly shortly after.

13 Q. What was the work environment or the atmosphere at NMT
14 surrounding these products to develop a retrievable filter?

15 A. It was a great place to work. He had very smart people
16 doing something nobody else had ever done, literally, and
17 trying to create a device that could save a lot of people's
18 lives and very collegiate, very academic, but very driven at
19 the same time.

03:21PM

20 Q. Now, at some point NMT sold its rights to the Recovery
21 Filter to C.R. Bard, correct?

03:21PM

22 A. Yes. I believe October of 2001.

23 Q. And did NMT also sell the rights to the Simon Nitinol
24 Filter at that time?

25 A. Yes.

03:21PM

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1 Q. And then how soon after that sale did you move to Bard?

2 A. I started July 1st, so about nine months.

3 Q. Why did you decide to move to Bard in July of 2002?

4 A. It was a great opportunity, both for my family -- my oldest
5 children were just about to start kindergarten. My wife had
6 graduated from school and the opportunity to continue to
7 develop filters and work for a larger, more stable medical
8 device company.

03:22PM

9 Q. And so when you moved to Bard, did you receive the
10 opportunity to continue to work with IVC filters?

03:22PM

11 A. I did, yes.

12 Q. And what was your position when you moved to Bard?

13 A. It was program director.

14 Q. And did any of your other colleagues at NMT eventually join
15 you at Bard?

03:22PM

16 A. Yes. Ultimately, I brought Andrzej Chanduszko from NMT to
17 Bard.

18 Q. Had you worked with Mr. Chanduszko while at NMT in filter
19 development projects?

20 A. Yes. In fact, we started the same day.

03:23PM

21 Q. When you came over to Bard did you continue to work with
22 Dr. Kaufman and Dr. Venbrux as consultants on the projects?

23 A. Yes, we did.

24 Q. Mr. Carr, let's talk a little bit about your experience as
25 a biomedical engineer in the development of new medical

03:23PM

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1 devices.

2 Could we bring up slide 6089 -- Exhibit 6089.

3 Are you familiar with this document?

4 A. Yes. I created it.

5 Q. And what is this document?

03:23PM

6 A. It's an outline that walks through our new product
7 development system, or the way we develop products.

8 Q. Have you used this particular presentation on the job at
9 Bard?

10 A. Yes.

03:23PM

11 Q. In what kind of context?

12 A. To outline the way we do things and what we focus on, our
13 steps through the development cycle.

14 MR. NORTH: Your Honor, at this time we would offer
15 for admission Exhibit 6089.

03:24PM

16 MR. O'CONNOR: No objection, Your Honor.

17 THE COURT: Admitted.

18 MR. NORTH: Could we display, Your Honor?

19 THE COURT: Yes.

20 MR. NORTH: Could we turn to Page 3.

03:24PM

21 BY MR. NORTH:

22 Q. If you would, Mr. Carr, walk through for the jury what you
23 are attempting to depict here regarding the new product
24 development process.

25 A. So what this slide says, if you work from left to right,

03:24PM

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1 yeah, my left to right, you start with ideas. And so, you
2 know, our business is based on creating needs out of unmet
3 needs so there are ideas of those solutions. As those ideas
4 percolate we put together a business case to hopefully either
5 pursue those ideas or not. And that's where you see your
6 approved idea, POA, which is product opportunity assessment.

03:24PM

7 If successfully passing through that gate, we enter
8 what's called the concept phase where we take some of those
9 ideas and hopefully make them more real; so potential
10 solutions, some prototypes, if you will. We do some testing.
11 And the goal of concept phase is really to eliminate all of the
12 show stoppers or unmet questions.

03:25PM

13 We then go through a design review where that's
14 reviewed by independent people off of the project. Feasibility
15 is a continuation of that process where those ideas and
16 prototypes are further refined. We develop all the design
17 inputs, all the specifications. We hold another design review
18 to say that, yes, those are what we want the product to be.
19 Then through development, we actually build samples for testing
20 through all of our, what's called, verification and validation
21 testing. Go through yet another design review to make sure
22 those outputs have met the inputs that were created before and
23 then get another approval to launch the product obviously
24 assuming that we had regulatory approval before that.

03:25PM

03:26PM

25 And then once the product is on the market for some

03:26PM

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1 period of time we do a post-launch design review where we take
2 in all of the data that we have had from complaints, from
3 sales, from operational efficiencies, things like that and hold
4 yet another design review.

5 Q. If we could turn to Page 13 on that very topic.

03:26PM

6 Why do you conduct a post-launch review and an
7 additional design review even though the product is already out
8 on the market?

9 A. To double check that things are going well; to assess where
10 that product is, and again, from both externally looking out
11 into the field as well as internally looking from a production
12 and cost and operations point of view.

03:27PM

13 Q. When the G2 and the Eclipse filters were being designed and
14 developed, was this general product development cycle followed?

15 A. Yes.

03:27PM

16 Q. Mr. Carr, over the course of your years, have you been
17 actively involved with engineering issues at Bard Peripheral
18 Vascular?

19 A. Sure.

20 Q. And for a lot of that time, have you been involved with
21 filters specifically?

03:27PM

22 A. Yes.

23 Q. Are you familiar generally with how much money the Division
24 has invested in the research and development of its filters?

25 A. Yes. Over \$18 million.

03:27PM

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1 Q. And would that stretch from 2003 to 2017?

2 A. Yes.

3 Q. Did they spend anywhere close to that amount of money that
4 they spent in research and development in marketing filters?

5 A. No, about one-third of that.

03:28PM

6 Q. Let's talk briefly about the Recovery Filter and its
7 development first.

8 Is it fair to say based on what you told us earlier
9 that the development of the Recovery Filter began in 1996 or
10 thereabouts?

03:28PM

11 A. Yes.

12 Q. Did NMT, you and your fellow team members at NMT have to
13 develop a number of prototypes for the Recovery Filter before
14 you settled on the ultimate design?

15 A. Yes, very many.

03:28PM

16 Q. And why were some prototypes rejected or not used?

17 A. For one reason or another, they failed our testing or were
18 maybe too difficult to make or were just not practical
19 solutions at the end of the day.

20 Q. When was the initial design of the Recovery Filter as it
21 ultimately came to be marketed, created, or invented?

03:29PM

22 A. Probably 1998-ish.

23 Q. So did it take you and your team approximately two years in
24 testing various prototypes to come up with the ultimate design?

25 A. Yes.

03:29PM

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1 Q. Once you arrived at what would be the ultimate design among
2 those various prototypes, what was the next step?

3 A. We would do benchtop testing.

4 Q. What type of tests did you perform on the proposed design
5 while at NMT?

03:29PM

6 A. They would be tests that ranged from testing the strength
7 of the device, tensile strength, to migration testing, to clot
8 trapping, to some animal tests where we looked at the filters
9 implanted, could they be removed without damaging the vena
10 cava. A whole battery of tests.

03:30PM

11 Q. In your 25-plus years in the medical device industry, have
12 bench tests been fairly typical in the product development
13 cycle?

14 A. Mandatory.

15 Q. And in developing and testing what became the Recovery
16 Filter, did NMT also conduct some animal tests?

03:30PM

17 A. Yes, we did.

18 Q. And what physicians assisted you with the animal tests?

19 A. Dr. Simon, but primarily Doctors Venbrux and Kaufman.

20 Q. And in the development of the Recovery Filter, did you also
21 ultimately conduct, or did NMT conduct a clinical study?

03:30PM

22 A. Yes. We did a special access study in Toronto with Dr.
23 Asch.

24 Q. In your experience, are clinical studies common for these
25 types of medical devices?

03:31PM

~~5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct~~

1 A. Yes.

2 Q. Are they typical or common for devices that go through the
3 510(k) process as opposed to the PMA or approval process?

4 A. No. Not routinely.

5 Q. If we could bring up Exhibit 5189. Do you recognize what
6 this is, Mr. Carr?

7 A. Yes.

8 Q. And what is it?

9 A. It is the special 510(k) submission filed in November of
10 2002.

11 Q. Was this the submission to the FDA for a permanent
12 indication for the Recovery Filter?

13 A. Yes.

14 Q. Was this submitted after you had already joined Bard?

15 A. Yes.

16 Q. And were you personally involved in preparing this
17 submission, Mr. Carr?

18 A. Yes.

19 MR. NORTH: Your Honor, at this time we would tender
20 5189.

21 THE COURT: I show it in evidence.

22 MR. NORTH: I'm sorry, Your Honor. Could we display
23 it, please?

24 THE COURT: You may.

25 BY MR. NORTH:

03:31PM

03:31PM

03:31PM

03:32PM

03:32PM

5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct

1 Q. Could we turn to Page 18, please.

2 What does this portion of the 510(k) generally depict?

3 A. It's the summary of the design control activities, so it
4 outlines on the left part of the table the changes or
5 modifications to the filter, the predicate device, and in the
6 bottom the delivery system, and then to the right the tests
7 that were performed based on those changes.

03:32PM

8 Q. If we could turn to Page 20, please.

9 What is clot trapping efficiency?

10 A. It's how well the filter performs its ultimate function
11 which is to stop clots from going to the lungs which is called
12 a pulmonary embolism.

03:32PM

13 Q. If we could look down at the bottom of that page under
14 summary, did Bard provide the FDA with a summary of the test
15 results regarding clot trapping efficiency that the company had
16 performed?

03:33PM

17 A. Yes, we did.

18 Q. Now, Mr. Carr, to be clear, were some of the tests that
19 Bard was submitting to the FDA tests that had been performed
20 with your or Mr. Chanduszek's involvement while still at NMT?

03:33PM

21 A. Yes.

22 Q. Were there other tests that you performed or various
23 engineers performed once you moved to Bard that were also part
24 of the submission?

25 A. Yes.

03:33PM

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1 Q. If we could turn to Page 21, please.

2 What is this particular test that you are describing
3 for the FDA?

4 A. It's the migration test that was performed.

5 Q. Did the -- looking down at this summary did the company
6 again provide the FDA with a summary of the test results
7 regarding migration resistance?

8 A. Yes, we did.

9 Q. And let's turn to Page 23, please.

10 Is the same true for tests performed by NMT and Bard
11 concerning weld, integrity, and hook strength for the device?

12 A. Yes, it is.

13 Q. And again, was all of that information shared with the FDA?

14 A. Yes.

15 Q. If we could turn to Page 24, please. Corrosion fatigue
16 testing. Did the company share with the FDA, again, all
17 information concerning those tests that had been performed on
18 the Recovery Filter?

19 A. Yes, we did.

20 Q. And then if we could turn to Page 25. Is the same thing
21 true with regard to radial strength testing?

22 A. Yes.

23 Q. 26, please.

24 The same with simulated use testing?

25 A. Yes.

03:34PM

03:34PM

03:34PM

03:35PM

03:35PM

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1 Q. What is simulated use study?

2 A. It studied the ability to deploy the filter and then how
3 the filter centered in the vessel that it was put into as well
4 as the forces and trackability, we call it, so the ability to
5 track through the tortuous vessels to the site that you want to
6 implant it.

03:35PM

7 Q. If we could turn to Page 29.

8 Did Bard, in this submission in November of 2002,
9 provide the FDA with information in a detailed summary of the
10 study, clinical study, conducted by Dr. Murray Asch?

03:35PM

11 A. Yes.

12 Q. If we could turn to Page 33, please.

13 Now, we heard testimony, this jury heard testimony
14 couple weeks ago about two patients who had complications in
15 that study. Do you recall those patients?

03:36PM

16 A. Yes.

17 Q. And were they referred to as Patient Number 9 and Patient
18 Number 33?

19 A. Yes.

20 Q. In this submission to the FDA to obtain clearance for the
21 Recovery Filter in November of 2002, did Bard provide
22 information to the agency about those complications reported in
23 the Asch study?

03:36PM

24 A. Yes.

25 Q. And did you also provide information here to the agency

03:36PM

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1 about your investigation of those complications?

2 A. Yes.

3 Q. If we could bring up 5187.

4 MR. NORTH: I believe this is admitted. Oh. I'm
5 sorry, Your Honor.

03:37PM

6 BY MR. NORTH:

7 Q. Tell us what 5187 is, Mr. Carr.

8 A. It is a response by the FDA to our submission where they
9 asked us a series of questions.

10 Q. And have you seen those questions before?

03:37PM

11 A. Yes, I have.

12 Q. And were you involved in helping prepare Bard's response to
13 those questions?

14 A. Yes.

15 MR. NORTH: Your Honor, at this time we would tender
16 5187 for admission.

03:37PM

17 MR. O'CONNOR: We have no objection, Your Honor.

18 THE COURT: Admitted.

19 MR. NORTH: May we display, Your Honor?

20 THE COURT: Yes.

03:37PM

21 MR. NORTH: Thank you.

22 BY MR. NORTH:

23 Q. Scroll down to the last page, if you would. Go back one
24 page, I'm sorry. One more.

25 How many questions total did the FDA pose to Bard

03:38PM

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1 regarding the submission?

2 A. 17.

3 Q. And this letter is dated August of 2002. Is that correct,
4 the first page, please?

5 A. Yes, August 5th.

03:38PM

6 Q. And I may have misspoke earlier referring to the actual
7 510(k) as dated November of 2002. Is that date the actual date
8 that it was cleared?

9 A. Yes. I believe so.

10 Q. Let's look at Page 2, if we could.

03:38PM

11 In Question 3, what -- 3, 4, and 5, what is the agency
12 asking the company regarding the testing information that had
13 been provided in the 510(k)?

14 A. All three are in response or on the subject of clot
15 trapping efficiency. And so Question Number 4, they are asking
16 for the data for the test. And then Question 5 is a
17 clarification of the testing parameters.

03:39PM

18 Q. Okay. If we could look further down that page at Question
19 8. What is the agency requesting here?

20 A. Our testing that shows that the Recovery Filter doesn't
21 cause caval perforation, meaning it doesn't go through the
22 vessel.

03:39PM

23 Q. If we could look on the same page at Question 10. What is
24 the agency asking Bard about here?

25 A. For the data, again, behind the simulated use study.

03:39PM

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1 Q. If we could turn to Page 3, please.

2 Let's look at Questions 11 through 13, please. What
3 is the agency interested in here?

4 A. A lot of the force testing. So the first one is the weld
5 integrity and hook strength, which is a measure of how strongly
6 the wires are welded to the top of the device. Question 12 is,
7 again, they are asking for the protocol and the results.

03:40PM

8 Q. If we could go down to Question 14, please. What is the
9 agency asking about here?

10 A. A radial strength test.

03:40PM

11 Q. And then if we could look together at 15 and 16.

12 A. It's about biocompatibility.

13 Q. Now, if we could bring up Exhibit 5182, please.

14 Do you recognize what this document is?

15 A. Yes.

03:41PM

16 Q. What is it?

17 A. It is our responses to those questions.

18 Q. And what is that dated?

19 A. August 30, 2002.

20 MR. NORTH: Your Honor, at this time we would offer
21 for admission Exhibit 5182.

03:41PM

22 MR. O'CONNOR: No objection, Your Honor.

23 THE COURT: Admitted.

24 BY MR. NORTH:

25 Q. What sort of information did Bard provide the agency in

03:41PM

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1 response to those 17 questions they had posed?

2 A. As much information as we could. Certainly whether they --
3 some of them had just asked for protocols and test methods so
4 we provided them our documentation for that. Where it required
5 further testing we would have done that. We tried to answer
6 each question as thoroughly and responsibly as possible.

03:41PM

7 Q. If we could look at Page 11, please.

8 MR. NORTH: Could we display, Your Honor?

9 THE COURT: You may.

10 BY MR. NORTH:

03:42PM

11 Q. Did Bard respond to the agency's questions regarding
12 corrosion and fatigue testing?

13 A. Yes.

14 Q. By providing what sorts of information?

15 A. We provided our cyclical testing that we did at the time
16 per standard. We also provided our fatigue testing at the
17 time.

03:42PM

18 Q. Did Bard actually provide test reports themselves to the
19 agency with these answers to the questions?

20 A. Yes.

03:42PM

21 Q. If we could turn to Page 30, please. For example, is this
22 a cyclic polarization testing that was provided as an appendix
23 to the letter response?

24 A. Yes, it is.

25 Q. 117, please. Next page. Is this the report on simulated

03:43PM

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1 use that you actually then submitted to the agency in
2 conjunction with that letter?

3 A. Yes.

4 Q. And were there a number of other similar type test reports
5 that you actually gave to the agency?

03:43PM

6 A. We would have given them anything that supported the
7 answer, so yes.

8 Q. So after that information was provided in that letter dated
9 August 30 of 2002, did you hear back from the FDA?

10 A. Yes. They had some more questions.

03:43PM

11 Q. If we could bring up Exhibit 5179, please.

12 What is this, Mr. Carr?

13 A. This is that letter back from them with their additional
14 questions.

15 Q. Were you involved on behalf of the company in preparing
16 responses to this letter?

03:43PM

17 A. Yes.

18 MR. NORTH: Your Honor, at this time we would offer
19 for admission Exhibit 5179.

20 MR. O'CONNOR: No objection, Your Honor.

03:44PM

21 THE COURT: Admitted.

22 MR. NORTH: May we display, Your Honor?

23 THE COURT: Yes.

24 BY MR. NORTH:

25 Q. Let's look at Question Number 1, if we could.

03:44PM

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1 What is the agency asking here with its follow-up
2 questions?

3 A. Further clarification on our clot trapping testing.

4 Q. Let's look at Question Number 2. What is the agency asking
5 about here?

03:44PM

6 A. Further clarification for a radial strength testing.

7 Q. Let's highlight the first line, if we could.

8 Is the FDA in this letter specifically referencing its
9 guidance that was published in 1999 for filters?

10 A. Yes, it is.

03:45PM

11 Q. And if we could turn to the next page, please.

12 Looking at Question 3, about midway down that
13 paragraph, does the agency ask you to revise your indications
14 for use?

15 A. Yes, they do.

03:45PM

16 Q. Now, if we could bring up Exhibit 5178, please. What is
17 this?

18 A. That's our responses to their second round of questions.

19 Q. Now --

20 MR. NORTH: Well, Your Honor, at this time we would
21 tender Exhibit 5178 for admission.

03:45PM

22 MR. O'CONNOR: No objection.

23 THE COURT: Admitted.

24 MR. NORTH: May we display, Your Honor?

25 THE COURT: Yes.

03:45PM

—5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct—

1 BY MR. NORTH:

2 Q. Mr. Carr, just so we're not all confused here, this list or
3 seems to be on the letterhead of a company called IMPRA. Could
4 you tell us what IMPRA was?

5 A. It was the former name of what is now Bard Peripheral
6 Vascular.

7 Q. At the top left does it identify IMPRA as a subsidiary of
8 C.R. Bard?

9 A. Yes, it does.

10 Q. So did Bard provide various information to the FDA in this
11 letter in response to the second round of questions the agency
12 had?

13 A. Yes.

14 Q. If we could bring up Exhibit 5177, please.

15 And is this the letter from the agency providing
16 clearance for the Recovery Filter for permanent indication?

17 A. It is their concurrence letter, yes.

18 MR. NORTH: Your Honor, I think this one may be
19 admitted.

20 THE COURT: 5177? No.

21 MR. NORTH: Then I would tender it for admission, Your
22 Honor.

23 MR. O'CONNOR: No objection.

24 THE COURT: Admitted.

25 MR. NORTH: And could we display, Your Honor?

03:46PM

03:46PM

03:46PM

03:47PM

03:47PM

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1 THE COURT: Yes.

2 BY MR. NORTH:

3 Q. What's the date of this again, Mr. Carr?

4 A. November 27th, 2002.

5 Q. And is that the same date that we saw on the actual 510(k)
6 submission that we viewed earlier?

03:47PM

7 A. Yes, it is.

8 Q. Now, did Bard thereafter submit an additional 510(k) for
9 the Recovery Filter to obtain clearance as a retrievable
10 device?

03:47PM

11 A. Yes, we did.

12 Q. Let's bring up 5169.

13 Is this a copy of the application for clearance as a
14 retrievable filter?

15 A. Yes.

03:47PM

16 Q. And this shows a date of July 25, 2003?

17 A. Yes.

18 Q. Again, is that the date that the application was ultimately
19 cleared?

20 A. I'd have to look inside to be sure.

03:48PM

21 MR. NORTH: Your Honor, at this time if not already
22 admitted we would tender 5169.

23 MR. O'CONNOR: No objection.

24 THE COURT: Admitted.

25 MR. NORTH: Could we display, please?

03:48PM

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1 THE COURT: You may.

2 BY MR. NORTH:

3 Q. Let's look at the second page, if we could.

4 Does this demonstrate what date this was actually
5 first submitted to the FDA?

03:48PM

6 A. Yes. April 25th.

7 Q. Did the FDA ultimately clear the device for retrievable
8 use?

9 A. Yes, they did.

10 Q. As a part of this submission, did you provide the FDA with
11 additional information more than you had previously provided
12 with the first 510(k)?

03:48PM

13 A. Yes.

14 Q. Did that include additional clinical information from the
15 Asch study?

03:49PM

16 A. Yes, it did.

17 Q. Did that include animal study information?

18 A. Yes.

19 Q. If we could bring up Exhibit 5197, please.

20 And what is 5197?

03:49PM

21 A. It is the FDA's letter agreeing with us and their
22 concurrence letter.

23 Q. And did that clear the device for sale as a retrievable
24 filter in this country?

25 A. Yes, it did.

03:49PM

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1 MR. NORTH: Your Honor, at this time we would tender
2 for admission Exhibit 5197.

3 MR. O'CONNOR: No objection.

4 THE COURT: Admitted.

5 MR. NORTH: And could we display?

03:49PM

6 THE COURT: Yes.

7 BY MR. NORTH:

8 Q. Mr. Carr, when did Bard start the development process for
9 the G2 filter?

10 A. Sometime in early 2004.

03:50PM

11 Q. Why did Bard decide to start developing the G2 Filter?

12 A. We thought we could make an improved device. For all of
13 our devices we were constantly trying to make the next
14 generation device that is better and to replace ourselves
15 rather than have somebody else replace us.

03:50PM

16 Q. And were there specific design attributes of the Recovery
17 Filter that Bard hoped to improve with the G2 Filter?

18 A. Yes. We wanted to improve migration and fracture
19 resistance.

20 Q. What is a product performance specification?

03:50PM

21 A. It is the document that outlines how you want the device to
22 behave so the design inputs that I mentioned earlier are
23 referenced in this document. So how big it is, how tall it is,
24 how -- what size sheath it needs to go through, the performance
25 criteria that you want the device to have.

03:51PM

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1 MR. NORTH: If we could bring up Exhibit 5296, please.

2 And bring up the second page, please.

3 BY MR. NORTH:

4 Q. Can you identify what this is, Mr. Carr?

5 A. It is the PPS, or performance -- Product Performance
6 Specification for the G2 Filter.

03:51PM

7 MR. NORTH: Your Honor, at this time we would offer
8 for admission Exhibit 5296.

9 THE COURTROOM DEPUTY: I show it in.

10 MR. O'CONNOR: No objection.

03:51PM

11 THE COURT: We show it in evidence.

12 MR. NORTH: I'm sorry, Your Honor. Could we display?

13 THE COURT: Yes.

14 BY MR. NORTH:

15 Q. If we could turn to Page 17, please. What does this mean
16 by "design input"?

03:52PM

17 A. Again, we have what we want the device to be, both from a
18 user point of view as well from how that translates to an
19 engineering specification.

20 Q. And if we could look under user requirement for filter
21 migration resistance. And what was the aim for the G2 Filter?

03:52PM

22 A. That the filter be statistically -- the migration
23 resistance of the filter be statistically greater than that of
24 the Recovery Filter in a 28 millimeter diameter simulated IVC
25 or vessel.

03:52PM

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1 Q. And under pass or fail, did the G2 pass or fail these
2 criteria?

3 A. It ultimately passed.

4 Q. Let's talk -- were there also some animal tests performed
5 on the G2 Filter?

03:53PM

6 A. Yes.

7 Q. And are there two types of animal tests that are generally
8 performed?

9 A. Yes. We did what's called chronic testing, which is
10 shorter term, and then we did testing where we implanted
11 filters for a longer time and tried to remove them.

03:53PM

12 Q. If we could bring up Exhibit 5301.

13 Do you recognize what this is?

14 A. Yes.

15 Q. What is this?

03:53PM

16 A. It's a test report from the G2 animal study.

17 MR. NORTH: Your Honor, at this time we would offer
18 5301.

19 MR. O'CONNOR: Your Honor, just foundation in terms of
20 date or time of this document, please.

03:53PM

21 THE COURT: Mr. North, can you lay that foundation?

22 MR. NORTH: Bring up the second page for Mr. Carr, if
23 you would.

24 BY MR. NORTH:

25 Q. Can you tell the general time frame of this test was

03:54PM

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1 performed by looking at the second page?

2 A. Yes. It's January of 2005.

3 MR. O'CONNOR: Thank you. I appreciate that. No
4 objection.

5 THE COURT: 5301 is admitted.

03:54PM

6 MR. NORTH: If we could turn back to the first page.
7 If we could display, Your Honor.

8 THE COURT: You may.

9 BY MR. NORTH:

10 Q. What is meant here where they call it the Recovery Filter
11 G1A?

03:54PM

12 A. Just the name of the filter that ultimately became G2.

13 Q. Is this the chronic or the acute animal study or can you
14 tell?

15 A. I would have to see the next page.

03:54PM

16 Q. Okay. Let's see the next page, if we could.

17 A. Probably the next one. Sorry. Probably the next one.
18 There. I'd have to see the outline of the study.

19 I can't tell off the top of my head here. Sorry.

20 Q. Tell you what. Let's bring up Exhibit 5034 if we can. And
21 do you recognize what this is?

03:55PM

22 A. Yes. This is the chronic report.

23 Q. So is this a separate animal study than the one we were
24 just looking at?

25 A. Yes.

03:55PM

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1 Q. If we could look at the next page. Was this performed in
2 early 2005 also?

3 A. Yes, in March.

4 MR. NORTH: Your Honor, at this time we would offer
5 for admission 5304.

03:55PM

6 MR. O'CONNOR: No objection.

7 THE COURT: Admitted.

8 MR. NORTH: If we could display, Your Honor.

9 THE COURT: You may.

10 BY MR. NORTH:

03:56PM

11 Q. Does this indicate that Andrzej Chanduszek was involved in
12 approving the test on behalf of the engineering department?

13 A. Yes, it does.

14 Q. And if we could turn to Page 11, please.

15 Looking at the second paragraph towards the -- it's
16 talking about physician investigators. Do you recall who the
17 physician investigators were assisting with the animal studies?

03:56PM

18 A. Yes. It was Dr. Venbrux and Dr. Kaufman.

19 Q. Did Bard also perform bench testing when developing the G2?

20 A. Yes.

03:56PM

21 MR. NORTH: If we could bring up Exhibit 5302. I
22 believe this is already admitted.

23 THE COURT: It is.

24 MR. NORTH: Could we display, Your Honor?

25 THE COURT: Yes.

03:56PM

—5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct—

1 BY MR. NORTH:

2 Q. And are you familiar with this, Mr. Carr?

3 A. Yes, I am.

4 Q. And tell us just -- we have heard a little bit of testimony
5 about it. Tell us generally what this is.

03:57PM

6 A. So this is the protocol on how to conduct our verification
7 and validation testing for what became the G2 Filter.

8 Q. What is design verification?

9 A. It's showing that your design meets your design inputs.

10 Q. And what is design validation as opposed to -- as it may
11 differ from verification?

03:57PM

12 A. You are validating that it meets your user needs.

13 MR. NORTH: If we could bring up Exhibit 5303. I
14 believe that's admitted also if we could display, Your Honor.

15 THE COURT: You may. I.

03:57PM

16 BY MR. NORTH:

17 Q. Is this the actual design verification and validation
18 report regarding the G2?

19 A. Yes, it is.

20 Q. If we could look at Page 9, please. Does this begin a
21 section talking at the top of the page about test results and
22 summary of data?

03:57PM

23 A. Yes, it does.

24 Q. And what is this particular test?

25 A. This is a dimensional test of the outer diameter of the

03:58PM

5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct

1 dilator which is the sheath that the filter goes through.

2 Q. And did the G2 pass this test?

3 A. Yes, it did.

4 Q. If we could turn to Page 12, please. Is this the same sort
5 of simulated use test that the FDA had asked all those
6 questions about with regard to the Recovery Filter?

03:58PM

7 A. Yes.

8 Q. Does this contain the results of the simulated use test on
9 the G2?

10 A. Yes, it does.

03:58PM

11 Q. And how did the G2 fare with that testing?

12 A. It passed all the tests.

13 Q. If we look down at the left, next to the last row, filter
14 centering. What is that assessing with regard to the filter?

15 A. So when you deploy the filter into the tube, you measure
16 where the tip of the filter is with respect to the center of
17 the vessel.

03:59PM

18 Q. If we could turn to Page 13, please.

19 What is filter leg radial strength? What are you
20 measuring there?

03:59PM

21 A. You are measuring the force that a leg of the filter exerts
22 outward.

23 Q. Did the G2 pass that particular test?

24 A. Yes, it did.

25 Q. Let's look on the same page at Section 7.6. What does

03:59PM

—5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct—

1 filter removal force assess?

2 A. It is the force that it takes to remove the filter from the
3 vessel.

4 Q. And did the G2 pass that test?

5 A. Yes, it did.

04:00PM

6 Q. Let's go to Page 14, please. Looking at the first one up
7 there, what is tensile strength test results? What's that
8 assessing?

9 A. So it measured two different joints or bonds. We have a
10 dilator to the hub of the dilator, which is how you attach to
11 it, and then the spline is a piece of the delivery system to --
12 it sits on a wire. And so we measure the force required to
13 separate them or remove the spline from the wire.

04:00PM

14 Q. Did the G2 pass these tests?

15 A. Yes, it did.

04:00PM

16 Q. If we could look on the same page at the bottom regarding
17 filter migration test results. Do you see that?

18 A. Yes, I do.

19 Q. Was this a particular aim for the G2 development?

20 A. Yes.

04:01PM

21 Q. And is this testing the stability of the filter when hit by
22 a large clot?

23 A. Yes.

24 Q. And so is it testing migration resistance to migration from
25 a cephalad direction, or going up?

04:01PM

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1 A. Going cranially, yes, from the bottom.

2 Q. And why would you do this test with different sizes of
3 cavas?

4 A. To try and show the range of anticipated vessel sizes and
5 test the filter in a small lower limit and then 28 is the upper
6 limit that the filter is indicated for.

04:01PM

7 Q. Let's go to Page 15, if we could. And let's look at the
8 bottom table.

9 This table indicate how the G2 compared to the
10 Recovery Filter in the migration resistance?

04:02PM

11 A. Yes, it does.

12 Q. And what column can you see that best demonstrates that
13 comparison?

14 A. The mean, or the third column from the left.

15 Q. Does that indicate that -- well, the G1A was the G2?

04:02PM

16 A. Yes.

17 Q. And was this migration, the mean for its migration
18 resistance, almost twice that of the Recovery Filter?

19 A. Yes, it is.

20 Q. And the abbreviation on the title for the table mmHg, what
21 does that stand for?

04:02PM

22 A. Millimeters of mercury.

23 Q. And tell us briefly what that is as a means of measurement
24 here?

25 A. It's a pressure -- way to measure pressure, so like your

04:03PM

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1 blood pressure or something else.

2 Q. Now, there's been some suggestion that the G2 failed this
3 test somehow because its mean for migration resistance was less
4 than the Simon Nitinol. Did that concern you?

5 A. No.

04:03PM

6 Q. Why is that?

7 A. Because the intent of the program was to improve the
8 Recovery Filter to create the G2. We have competitive testing
9 which showed that the G2 is now very comfortably in the upper
10 range of competitive devices, and we felt that that migration
11 resistance was more than adequate.

04:03PM

12 Q. Did the company share this design verification and
13 validation test report with the FDA?

14 A. Yes, we did.

15 Q. And was the FDA aware of how the migration resistance of
16 the G2 compared both to the Recovery Filter and the Simon
17 Nitinol Filter?

04:04PM

18 A. Yes. We separated it out and explained our rationales.

19 Q. Let's look at Page 21, if we could, section 9.16. Is this
20 a discussion of the migration resistance of the G2 versus the
21 Simon Nitinol?

04:04PM

22 A. Yes, it is.

23 Q. And what does it mean when it says the testing did not meet
24 the acceptance criteria as defined in the protocol?

25 A. So the initial acceptance criteria was to be statistically

04:05PM

—5-29-18-MD 15-2641-Jones v Bard-Jury Trial-Day 9-Carr-Direct—

1 equivalent to the Simon Nitinol Filter or greater, and it did
2 not meet that specification. But again, the goal of the
3 project was to be significantly better than the Recovery
4 Filter.

5 Q. And then in the next line, what did you conclude with
6 regard to the G2 as compared to the Recovery Filter?

04:05PM

7 A. That it was significantly better.

8 Q. And again, was all of this shared with the FDA?

9 A. Yes, it was.

10 Q. Could we bring up Exhibit 5252, please.

04:05PM

11 Do you recognize what this test report is?

12 A. Yes, I do.

13 Q. And what is this?

14 A. It's a characterization study that we did on competitive
15 devices.

04:06PM

16 MR. NORTH: Your Honor, at this time we would tender
17 5252.

18 MR. O'CONNOR: No objection. Thank you.

19 THE COURT: Admitted.

20 MR. NORTH: Could we display, Your Honor?

04:06PM

21 THE COURT: Yes.

22 BY MR. NORTH:

23 Q. Let's turn to Page 6, if we could, please. There are a lot
24 of abbreviations under the left sample ID. Can you tell us,
25 are those identifying various filters that were being tested?

04:06PM

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1 A. Yes, it is.

2 Q. And what are some of those filters?

3 A. RF stands for Recovery; SF stands for Simon Nitinol; GT is
4 Greenfield; GS is Stainless Steel Greenfield; VT is the Vena
5 Tech Filter; TP is the Tulip Filter; O is the OptEase Filter;
6 and T is the Trapease Filter.

04:07PM

7 Q. If we could then highlight the mean section. I believe we
8 saw earlier that the mean migration resistance for the G2 was
9 approximately 106.3 millimeters of mercury?

10 A. Yes.

04:07PM

11 Q. And how did that test result compare to a lot of the
12 competitors here?

13 A. It was greater than all of the filters but the Trapease and
14 the OptEase.

15 Q. Now, as a part of the development of the G2, did Bard also
16 conduct a finite element analysis?

04:07PM

17 A. Yes.

18 Q. If we could bring up Exhibit 5307.

19 And can you identify this?

20 A. This is a process FMEA.

04:08PM

21 Q. And if we could look at the second -- or I'm sorry. Go
22 back to the first page.

23 Is this for the G2?

24 A. Yes. But this isn't the FEA, I don't believe.

25 Q. I'm sorry. I juxtaposed numbers. Let's try 5037. It's

04:08PM

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1 getting late in the day, I think.

2 Do you recognize 5037? And if so, what is this?

3 A. Yes. This is the report for the FEA analysis.

4 Q. Was this for the G2?

5 A. Yes.

04:09PM

6 MR. NORTH: Your Honor, at this time we would tender

7 5037.

8 THE COURT: It's already any evidence.

9 MR. NORTH: Thank you, Your Honor. Could we display?

10 THE COURT: You may.

04:09PM

11 BY MR. NORTH:

12 Q. Was the express purpose of this FEA to evaluate the effect
13 of the changes that had been made to the Recovery Filter to
14 create the G2?

15 A. Yes.

04:09PM

16 Q. Let's turn to Page 7, please.

17 Did Bard conduct this finite element analysis itself,
18 or did it employ an expert to do so?

19 A. No. We contracted out the work to Computer Aided
20 Engineering.

04:09PM

21 Q. And why did you do that?

22 A. As you pointed out, they are experts in finite element
23 analysis.

24 Q. And then if we could go to Page 4, please. And let's look
25 at test rationale. What does this indicate that the two

04:10PM

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1 filters were being assessed for?

2 A. So they were being assessed in both the loaded, which is
3 what we call when the filter's in the package before it's
4 delivered so it is constrained in a very small tube. So that's
5 the loaded condition. And then the deployed condition is in
6 the diameters that are the size of the vessel.

04:10PM

7 Q. Why did you decide to test it in two different scenarios?

8 A. The first one has to do with the ability to store the
9 device on a shelf, so part of it is aging or shelf life testing
10 and also where it's under the most load; and then in the
11 deployed condition because that's where the device is going to
12 operate.

04:10PM

13 Q. And then if we could turn to Page 5, please. And looking
14 at the conclusion, what was the conclusion?

15 A. That the modified filter in this case, the G2, shows
16 substantially lower peak stresses compared to the original
17 design up to 90 percent.

04:11PM

18 Q. And is that a good thing to have substantially lower peak
19 stresses?

20 A. Yes, it is.

04:11PM

21 Q. Now, it does say there's an exception with the legs.

22 Explain to us what that means.

23 A. So the legs of the G2 Filter in its resting dimension is
24 wider than the resting dimension of the Recovery Filter. So
25 the same leg, because it's further out, will impart more force

04:11PM

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1 outward so the stress is higher in that element.

2 Q. Now, we have talked generally, I know we haven't covered
3 every single test, we have talked generally about the bench
4 testing that was performed for the G2 Filter, correct?

5 A. Yes.

04:12PM

6 Q. And were there additional tests performed after the initial
7 design verification and validation report?

8 A. Yes, there was.

9 Q. Let's bring up Exhibit 5949, please.

10 Do you recognize what that is?

04:12PM

11 A. Yes, I do.

12 Q. What is this?

13 A. It is a clot trapping test.

14 Q. And I believe this is already admitted. No?

15 MR. NORTH: We tender for admission, Your Honor.

04:12PM

16 THE COURT: 5949?

17 MR. NORTH: Yes.

18 MR. O'CONNOR: One second, please.

19 No objection. Thank you.

20 THE COURT: Admitted.

04:12PM

21 MR. NORTH: And if we could display, Your Honor.

22 THE COURT: You may.

23 BY MR. NORTH:

24 Q. Tell us, Mr. Carr, why Bard, after you had already -- well,

25 I'm sorry. Let me back up.

04:13PM

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1 This appears to have been performed in 2006. Does
2 that look correct?

3 A. Yes, in May, I believe.

4 Q. Was the G2 already on the market at that time being sold?

5 A. Yes, it was.

04:13PM

6 Q. What was the impetus behind doing this test after the
7 product was already being sold?

8 A. We wanted to confirm that the product would operate as
9 intended if it happened to be tilted, meaning would it still
10 trap clots and prevent pulmonary embolism.

04:13PM

11 Q. Did you compare the G2 to some other specific filter?

12 A. The Greenfield Filter, which was the gold standard for clot
13 trapping.

14 Q. And why did you choose the Greenfield Filter?

15 A. Again, because it was the filter that everyone compared to
16 for clot trapping.

04:13PM

17 Q. Let's turn to Page 14 of this exhibit, please. Does this
18 indicate under "conclusion" how the G2 performed in this test?

19 A. Yes. It's hard to read, but --

20 Q. It is, isn't it? It's easier to read without the blowup, I
21 think.

04:14PM

22 And how did the G2 generally perform?

23 A. That the clot trapping efficiency, which is what it's
24 called, was greater than the Greenfield Filter tilted in the
25 tube.

04:14PM

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1 Q. Now, once Bard completed the design verification and
2 validation testing, what does the company do next? Do you
3 perform a design review?

4 A. Yes.

5 Q. And what's the purpose of that design review at that stage
6 of the development process?

04:14PM

7 A. It is to review all of the testing that's done to date,
8 again, to confirm and reconfirm that all of the design inputs
9 have been met and that we have statistically shown them to be
10 met and approve the submission of that data to the FDA and, in
11 this case, a 510(k).

04:15PM

12 Q. If we could bring up Exhibit 5315, please.

13 Could you identify what that is?

14 A. It's the cover page for that meeting.

15 Q. Did you participate in the design review for the G2?

04:15PM

16 A. I think so, but I don't remember 100 percent. If you go to
17 the next page. And the next one. So I wasn't at this one but
18 I was at subsequent ones.

19 MR. NORTH: Your Honor, if not already admitted we
20 would like to tender 5315.

04:15PM

21 MR. O'CONNOR: No objection.

22 THE COURT: Admitted.

23 MR. NORTH: If we could display, please.

24 THE COURT: You may.

25 BY MR. NORTH:

04:16PM

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1 Q. If we could turn to Page 21, please. What were the
2 conclusions of this design review regarding the G2?

3 A. That the filter demonstrated superior performance in
4 fatigue resistance to Recovery; demonstrated acceptable
5 performance in all the tests except for migration resistance
6 equivalence at 28 millimeters; and the G2 Filter demonstrated
7 superior performance in migration compared to the Recovery.

04:16PM

8 Q. The second bullet point you read, was that migration
9 resistance equivalent to the Simon Nitinol like we discussed
10 earlier?

04:16PM

11 A. Yes, it is.

12 Q. Let's look at 5316, please.

13 Is this another design review conducted for the G2
14 Filter?

15 A. Yes, it is.

04:17PM

16 Q. And did you participate in this one?

17 A. I believe so.

18 MR. NORTH: Your Honor, at this time we would offer
19 for admission Exhibit 5316.

20 MR. O'CONNOR: No objection.

04:17PM

21 THE COURT: Admitted.

22 MR. NORTH: Could we display, Your Honor?

23 THE COURT: You may.

24 BY MR. NORTH:

25 Q. If we could turn to Page 6, please. Under "Project Team

04:17PM

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1 Members," does that indicate that you participated?

2 A. Yes, it does.

3 Q. And there were a number of other people that participated
4 from all different types of functions around the company,
5 correct?

04:17PM

6 A. Yes.

7 Q. Let's turn to Page 7, if we could.

8 Objective. What does this define as the purpose for
9 this particular design review?

10 A. To review all the testing and documentation to ensure
11 compliance to design specifications and ensure that the device
12 will perform in a reliable, safe, and effective manner prior to
13 full market release.

04:18PM

14 Q. If we could turn to Page 9, please. What were the
15 conclusions from this particular review?

04:18PM

16 A. The design review team conditionally approved the review.
17 There was some extra items that needed to be completed prior to
18 final approval, which they ultimately were.

19 Q. Then if we could change gears.

20 THE COURT: If we're changing gears, we'll go ahead
21 and break until morning, Mr. North.

04:19PM

22 We'll plan, Ladies and Gentlemen, to resume at 9:00.
23 We'll see you then.

24 (Jury out at 4:19 p.m.)

25 THE COURT: You can step down, Mr. Carr. You can have

04:19PM

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1 a seat.

2 Start gathering up, counsel. I have a sentencing
3 starting in 10 minutes. If you can start gathering up your
4 stuff, I will calculate the time.

5 All right. Counsel, as of now, plaintiff has used 26
6 hours and 12 minutes and defendants have used 20 hours and 24
7 minutes.

04:22PM

8 Let's talk about tomorrow. How long do you anticipate
9 going tomorrow, Mr. North?

10 MR. NORTH: Certainly until after lunch, Your Honor.
11 I would think a minimum of 2 and more likely until 3 or so.

04:22PM

12 THE COURT: And what is your current thinking,
13 counsel, on rebuttal case?

14 MR. O'CONNOR: Well, Your Honor, we are talking about
15 it. I think we are planning on one. It would not be
16 significantly long. It may be a video deposition.

04:23PM

17 THE COURT: Okay. All right. Well, let's talk at
18 noon about where we are. Be prepared, if you would, please, to
19 talk about jury instructions in the morning.

20 I got some deposition excerpts from the plaintiff
21 today that looked like they were for the punitive damages case.
22 One thing that wasn't clear to me as I scanned the objections
23 from the defense was they were 403 and relevancy objections
24 citing the Supreme Court cases and saying that the numbers
25 should be limited to the Eclipse Filter in Georgia.

04:23PM

04:23PM

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1 My question was how that squares with what we did to
2 the jury instructions where we took out disgorgement of profits
3 as a factor and left in overall profitability.

4 MS. HELM: Your Honor, I think the objections were
5 left in simply to preserve them because that's where --

04:24PM

6 THE COURT: You are certainly entitled to preserve
7 them.

8 MS. HELM: And I believe that the issue that we
9 addressed in the jury instruction conference was actually
10 resolved. That testimony was withdrawn, the disgorgement
11 testimony was withdrawn.

04:24PM

12 MR. STOLLER: Correct. There's nothing but the stuff
13 we discussed with respect to what the jury instructions. We
14 will get the numbers that go to the financial worth of the
15 company and those sort of things.

04:24PM

16 THE COURT: All right. So were there any -- I don't
17 know if you remember this. Were there -- do I need to go
18 through line by line, or were there other objections besides
19 the one you are preserving to Georgia-based profits and limited
20 to the Eclipse Filter?

04:25PM

21 MS. HELM: No, Your Honor.

22 MR. STOLLER: There are some objections by plaintiffs
23 towards the end. They are discrete.

24 THE COURT: I don't plan to get through those tonight
25 since we're not going to be using them for a day or two if we

04:25PM

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1 use them.

2 MR. O'CONNOR: Your Honor, just quickly, tomorrow is
3 going to be a lot of evidence coming in. Just for scheduling
4 purposes in view of what Mr. North has indicated, can we safely
5 plan to start closings on Thursday morning?

04:25PM

6 THE COURT: Yes.

7 MR. O'CONNOR: Thank you.

8 THE COURT: Well, unless we're done with the evidence
9 by noon.

10 MR. NORTH: I will talk slowly.

04:25PM

11 THE COURT: You will put the jury to sleep. Okay.
12 Assuming we go until 2 in the afternoon, and I think it makes
13 sense to do closings on Thursday morning just because we
14 probably wouldn't get through them all tomorrow afternoon and
15 better to have a fresh jury for closings on Thursday morning.

04:25PM

16 MR. O'CONNOR: Also just for purposes of putting
17 together, I think there's going to be a lot of adjustments by
18 tomorrow because of the evidence.

19 THE COURT: Right. Okay. We'll see you tomorrow
20 morning at 8:30.

04:26PM

21 MS. HELM: Traci, can we work on the exhibits?

22 THE COURT: You can, outside the courtroom. I think
23 we need to close the courtroom for this sentencing.

24 MS. HELM: We'll take them in our little room and
25 Traci will let us know when she needs them.

04:26PM

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THE COURT: That's fine.

Is that okay with you, Traci?

(Proceeding recessed at 4:26 p.m.)

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 30th day of May, 2018.

s/Laurie A. Adams

Laurie A. Adams, RMR, CRR